Meddevicetracker Event Definitions

Meddevicetracker
Pharma Intelligence

Event Type Group	Event Type	Definition
Company	Divestment/Spinoff Announced	Company announces that a portion of its business will be divested/spun-off.
Company	Divestment/Spinoff Completed	Completion of the divestment/spin-off of this portion.
Corporate	Debt Conversion/Buyback	Company announces it has or is going to buy back shares or debt (i.e. convertible bonds, notes or debt)
Corporate	Name Change	Change in company name, however, not due to acquisition
Corporate	New Stock/Convertible Offering	Company announces plans of issuing or has issued new stock (including IPOs) or new debt, (i.e. convertible bonds, notes or debt)
Other	Company Public Statement	When a company issues a press release regarding a device or an event affecting the company that does not fall into any other specified category
Other	Device Name Change	To denote change in name by which device is most commonly referred
Other	Marketing Discontinuation	When a device is no longer being sold and removal from market was initiated by company
Other	Marketing Discontinuation (Emerging Markets)	When a device is no longer being sold and removal from market was initiated by company outside of the major markets (i.e. BRIC, etc.)
Other	Other	Any event that does not fall into any other specified category
Partnership	Acquisition Announcement	First announcement of deal or agreement of one company acquiring another, transaction to be completed usually within following months or quarters
Partnership	Acquisition Closed	Completion of transaction or deal of company acquiring another company or drug
Partnership	Amendment/Restructuring	Any change to licensing or partnership agreement terms (i.e. a change in responsibilities, payments, etc.)
Partnership	Amendment/Restructuring (Emerging Markets)	Any change to licensing or partnership agreement terms (i.e. a change in responsibilities, payments, etc.) that happens outside of the major markets (i.e. BRIC, etc.)
Partnership	Announcement	Any event relating to an agreement between companies that does not fall into any other specified event type (i.e. Federal Trade Commission communications in acquisitions, or updates on potential or pending licensing agreements)
Partnership	Announcement (Emerging Markets)	Any event relating to an agreement between companies that does not fall into any other specified event type (i.e. Federal Trade Commission communications in acquisitions, or updates on potential or pending licensing agreements) that happens outside of the major markets (i.e. BRIC, etc.)
Partnership	Cancellation	Any termination of agreement between companies

Partnership	Cancellation (Emerging Markets)	Any termination of agreement between companies that happens outside of the major markets (i.e. BRIC, etc.)
Partnership	Distribution Agreement	Company announces a “distribution agreement” but does not mention anything regarding licensing.
Partnership	Distribution Agreement (Emerging Markets)	Company announces a “distribution agreement” outside of the major markets (i.e. BRIC, etc.) but does not mention anything regarding licensing.
Partnership	Licensing Deal	Any new agreement (licensing, manufacturing, supply, etc.) between companies
Partnership	Licensing Deal (Emerging Markets)	Any new agreement (licensing, manufacturing, supply, etc.) between companies outside of the major markets (i.e. BRIC, etc.)
Partnership	Option Exercised	A decision made by a company to exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology
Partnership	Option Exercised (Emerging Markets)	A decision made by a company to exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology that happens outside of the major markets (i.e. BRIC, etc.)
Partnership	Option Not Exercised	A decision made by a company to not exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology
Partnership	Option Not Exercised (Emerging Markets)	A decision made by a company to not exercise its option in an agreement with another company, to either further develop or manufacture a certain compound or acquire a certain technology that happens outside of the major markets (i.e. BRIC, etc.)
Partnership	Product Acquisition	Company assumes all rights and responsibilities for a product from another company, which is no longer involved nor will receive any royalties for the product.
Partnership	Product Acquisition (Emerging Market)	Company assumes all rights and responsibilities for a product from another company outside of the major markets (i.e. BRIC, etc.)
Partnership	Vendor Relationship	Fee for service type of arrangement (e.g. CRO)
Patent	Application Rejection	US Patent and Trademark Office or European Patent Office rejects a company’s application for a patent or related items (i.e. patent term extension, patent reissue, etc.)
Patent	Application Rejection (Emerging Market)	An emerging market authority (i.e. BRIC, etc.) rejects a company’s application for a patent or related items (i.e. patent term extension, patent reissue, etc.)
Patent	Expiration/Invalidation	Medical device patent expired or no longer valid
Patent	Expiration/Invalidation (Emerging Markets)	Medical device patent expired or no longer valid in a nonmajor market (i.e. BRIC, etc.)

Patent	Extension	FDA grants an extension of exclusivity period to original expiration date of patent.
Patent	Litigation Update	Court decisions and rulings
Patent	New	US Patent and Trademark Office issues a patent
Patent	New (Emerging Markets)	A regulatory body issues a patent in a nonmajor market (i.e. BRIC, etc.)
Patent	Other	Anything related to a patent that is not covered in other patent definitions
Progress Update	Biomarker/Companion Diagnostic	Company update on diagnostic product associated with a drug (E.g. CO1.01 for Pancreatic Cancer). NOT used for partnership announcements regarding CDx.
Progress Update	Catalyst Insight	If further details are obtained from the company regarding recent events that causes a Scientific Analyst to analyze the current situation for the device taking several factors into account, warranting a change to catalyst analysis (expected event)
Progress Update	Compassionate Use	FDA grants a “compassionate use” provision for the use of a device prior to FDA approval for patients who do not meet the requirements for inclusion in the clinical investigation but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing their disease or condition. This provision is typically approved for individual patients but may be approved to treat a small group.
Progress Update	Development Review	Progress of overall clinical development program of device relates to its path to registration
Progress Update	Device Recall	Any Company- or FDA-initiated recall of a device or its components.
Progress Update	Hospital/Health System Product Launch	As opposed to a “Progress Update – Product Launch” event, this is used when a company launches a product noting a specific hospital or healthcare system instead of a broader commercial availability. Often used for larger device systems.
Progress Update	Manufacturing/Supply	Company update on issues regarding the ability to produce or supply the device.
Progress Update	Manufacturing/Supply (Emerging Markets)	Company update on issues regarding the ability to produce or supply the device in a nonmajor market (i.e. BRIC, etc.)
Progress Update	Product Launch (Australia)	Company launches approved device for sale in Australia
Progress Update	Product Launch (Canada)	Company launches approved device for sale in Canada
Progress Update	Product Launch (Emerging Markets)	Company launches approved device for sale in a nonmajor market (i.e. BRIC, etc.)
Progress Update	Product Launch (Europe)	Company launches approved device for sale in Europe
Progress Update	Product Launch (Europe) - Individual Country	Company launches approved device for sale in one European country
Progress Update	Product Launch (Japan)	Company launches approved device for sale in Japan

Progress Update	Product Launch (U.S.)	Company launches approved device for sale in the US
Progress Update	Product Relaunch	Company relaunches device that was previously removed from market temporarily for any reason
Progress Update	Program Hold	Company decides to no longer take a program forward by itself and sometimes seeks to outlicense device, due to lack of funds or strategic change in resources or company focus
Progress Update	Progress Update	An update on the progress of a device that does not fit into any other specified event type
Progress Update	Progress Update (Emerging Markets)	An update on the progress of a device that does not fit into any other specified event type specifically dealing with nonmajor markets (i.e. BRIC, etc.)
Progress Update	Safety Announcement	Company reported safety updates (as opposed to FDA's health advisory announcements)
Progress Update	Suspension	Company ceases development of device due to nonclinical reasons such as lack of finances or a change in strategy
Progress Update	Suspension (Emerging Markets)	Company ceases development of device in a nonmajor market (i.e. BRIC, etc.) due to nonclinical reasons such as lack of finances or a change in strategy
Regulatory	510(k) Clearance	This event type is used when the event is the first 510(k) clearance for a specific device. A 510(k) clearance is also required when a device currently marketed is changed. For 510(k) clearances pertaining to a specific change to a currently marketed device, see below.
Regulatory	510(k) Clearance - Amendment to Indication	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Amendment to Indication, should be used when the intended use or indication for a device has been altered or changed.
Regulatory	510(k) Clearance - Component/Accessory	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Component/Accessory, should be used when a component, piece, part, or accessory is added, changed, modified, or removed from the group of components that make up the cleared device. An example of this would be a cleared ablation system is additionally cleared for use with an additional probe, catheter, or generator. This can also be used when two previously cleared devices are cleared for use with each other.
Regulatory	510(k) Clearance - Design Change/Next Generation	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Design Change/Next Generation, should be used whenever there is a change or improvement pertaining to the design or functionality of a device. It is common for a specific device to go through many iterations (version 2.0, 3.0, 4.0….) which correspond with slight improvements or changes each time. If the company is marketing the next generation product as completely separate from its predicate and the functionality or design is changed enough to where the devices should be separated, it may be necessary to add a new device profile, in which case it would be simply designated a regular 510(k) clearance

Regulatory	510(k) Filing	Medical device manufacturers are required to submit a 510(k) application, also called premarket notification, if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Once submitted to the FDA, a 510(k) application usually takes about 90 days to be cleared but can take longer due to an application hold or an additional information (AI) request from the FDA. The majority of companies won't announce a 510(k) filing (see 510(k) Filing above), in which case a filing event would be retrospectively added once the approval is released containing the filing date.
Regulatory	510(k) Filing - Amendment to Indication	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Amendment to Indication, should be used when the company files a premarket notification intending to change the intended use or indication for a device. The majority of companies won't announce a 510(k) filing (see 510(k) Filing above), in which case a filing event would be retrospectively added once the approval is released containing the filing date.
Regulatory	510(k) Filing - Component/Accessory	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Component/Accessory, should be used when a company files a premarket notification intended to add, change, modify, or remove a component, piece, part, or accessory from the group of components that make up the cleared device. The majority of companies won't announce a 510(k) filing (see 510(k) Filing above), in which case a filing event would be retrospectively added once the approval is released containing the filing date.
Regulatory	510(k) Filing - Design Change/Next Generation	The FDA requires premarket notification (see 510(k) Clearance above) when a currently marketed device undergoes a change or modification. This event type, Design Change/Next Generation, should be used when a company files a premarket notification for a change or improvement pertaining to the design or functionality of a device. It is common for a specific device to go through many iterations (version 2.0, 3.0, 4.0….) which correspond with slight improvements or changes each time. The majority of companies won't announce a 510(k) filing (see 510(k) Filing above), in which case a filing event would be retrospectively added once the approval is released containing the filing date.
Regulatory	510(k) Not Substantially Equivalent	A device cannot be marketed if the FDA finds a subject device to be not substantially equivalent to a currently marketed device. From here, an applicant can: resubmit another 510(k) with new data, request a Class I or II designation through the de novo process, file a reclassification petition, or submit a Premarket Approval (PMA) application.
Regulatory	Approvable Letter	Receipt of approvable letter from FDA in response to 510(k) or PMA filing, can sometimes be resolved with submission of additional data or responses to specific issues
Regulatory	Approval (Australia)	Australian Therapeutic Goods Administration (TGA) grants approval to a new device
Regulatory	Approval (Canada)	Health Canada grants approval to a new device
Regulatory	Approval (Emerging Markets)	A regulatory body grants approval to market a device in a nonmajor market (i.e. BRIC, etc.)

Regulatory	Approval (Europe) – Individual Country	Device approval in a European country outside of the typical CE mark process
Regulatory	Biodefense Announcement	Announcement of communication or filing with FDA that is related to bioterrorism
Regulatory	CE Mark Approval	The CE mark, or formerly EC mark, is a mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985. The CE marking indicates a product's compliance with EU legislation and so enables the free movement of products within the European market. The CE mark approval means that EEA has approved the manufacturer's declaration that the product meets the requirements of the applicable EC directives.
Regulatory	CE Mark Filing	The CE mark, or formerly EC mark, is a mandatory conformity marking for certain products sold within the European Economic Area (EEA) since 1985. The CE marking indicates a product's compliance with EU legislation and so enables the free movement of products within the European market. The CE mark filing means that the Company has filed to get approval to declare that the product meets the requirements of the applicable EC directives
Regulatory	CLIA Waiver Designation	Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. With designation (approval), clinical tests are available for use in physician offices, clinics and other public health settings as well. A test with CLIA waiver designation is not to be confused with a laboratory developed test (LDT), which is a test only completed by the laboratory that created the test and is not commercially sold.
Regulatory	CLIA Waiver Submission	Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. Congress passed the Clinical Laboratory Improvement Amendments (CLIA) establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. A Company submits the CLIA waiver so that clinical tests can become available for use in physician offices, clinics and other public health settings as well.
Regulatory	Compassionate Use	A regulatory agency grants the manufacturer the ability to offer its product to patients under a compassionate use arrangement when the product has not received formal approval

Regulatory	De Novo Approval	Following the enactment of the FDA Modernization Act of 1997, FDA established a new regulatory route intended for medical devices that present a lower level of risk than those classified into Class III. The regulatory path is referred to as a 'De Novo' application, and involves two phases – an initial standard 510(k) process, followed by a review of the risk level of the technology – the De Novo review. In FDA's Guidance Document describing the De Novo application, the agency committed to completing the second phase – the De Novo review – within 60 days. To conclude, De novo approval is for new devices that have no predicate device to use for approval (different process than PMA and 510k). Once a device is cleared through the de novo process, it can be used as a predicate device for future 510(k) clearances.
Regulatory	De Novo Filing	Following the enactment of the FDA Modernization Act of 1997, FDA established a new regulatory route intended for medical devices that present a lower level of risk than those classified into Class III. The regulatory path is referred to as a 'De Novo' application, and involves two phases – an initial standard 510(k) process, followed by a review of the risk level of the technology – the De Novo review. In FDA's Guidance Document describing the De Novo application, the agency committed to completing the second phase – the De Novo review – within 60 days. To conclude, De novo filing is for new devices that have no predicate device to use for approval (different process than PMA and 510k). This is to be used when a company announces a filing under the De Novo pathway.
Regulatory	De Novo Request Denied	If the FDA finds that the device falls under Class III classification regulation or is not low-moderate risk the FDA will usually decline the de novo request. The company then has the option to file a Premarket Approval (PMA) or new de novo application. The FDA may also decline a de novo request if it finds that a Classification Review reveals a predicate device already 510(k) cleared, in which case the company will simply file a 510(k) application.
Regulatory	Emergency Use Authorization (EUA)	The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN (chemical, biological, radiological and nuclear) threats by facilitating the availability and use of MCMs needed during public health emergencies. The FDA Commissioner can allow either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency to diagnose, treat, or prevent a serious or life-threatening disease or condition caused by a CBRN agent if certain statutory criteria are met. When scientific evidence is available to support such a use in an emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating the FD&C Act.
Regulatory	Emergency Use Authorization (EUA) Submission	An EUA submission to the FDA
Regulatory	Expedited Access Pathway Designation	The Expedited Access Pathway is a new FDA program established April 2015 to facilitate patients gaining more rapid access to critical medical devices by expediting their development, assessment and review.
Regulatory	FDA Advisory Panel Brief	Release of and/or analysis of briefing documents from FDA site for upcoming Advisory Committee meeting

Regulatory	FDA Advisory Panel Meeting	Voting results, which FDA may take into consideration before issuing final decision
Regulatory	FDA Advisory Panel Meeting Cancelled/Postponed	FDA can cancel or postpone advisory committee meeting if deemed no longer necessary or more time is needed to review outstanding issues
Regulatory	FDA Advisory Panel Meeting Notification	Announcement of an upcoming FDA advisory panel meeting
Regulatory	FDA Advisory Panel Update	Update to upcoming panel (list of members, etc)
Regulatory	FDA Public Health Advisory	Safety warning issued by FDA
Regulatory	FDA Response	FDA issues a response to communication from Company that does not fall into other event types
Regulatory	Filing for Approval (Australia)	Company submits all the required regulatory documents seeking approval of a device in Australia
Regulatory	Filing for Approval (Canada)	Company submits all the required regulatory documents seeking approval of a device in Canada
Regulatory	Filing for Approval (Emerging Markets)	Company submits all the required regulatory documents seeking approval of a device in a nonmajor market (i.e. BRIC, etc.)
Regulatory	Filing for Approval Accepted (Canada)	Health Canada accepts new device submission filing
Regulatory	Green Channel (China)	China's Green Channel is a fast-track approval process for innovative devices that allows for an expedited registration process.
Regulatory	HDE Approval Decision	Humanitarian device exemption (HDE) application is approved by the FDA. An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
Regulatory	HDE Modular Filing	The modular HDE review process is based on a submission of individual sections or “modules” that constitute a complete HDE submission once all have been submitted. The modular approach allows the FDA to review each module separately, allowing the applicant to receive timely feedback and potentially resolve any deficiencies earlier in the review process compared to a traditional HDE application. Upon receipt of the final module, the FDA will make a filing decision that, if positive, triggers the HDE 75-day review clock for an approval decision.

Regulatory	HDE Modular Filing Completed	The modular HDE review process is based on a submission of individual sections or “modules” that constitute a complete HDE submission once all have been submitted. The modular approach allows the FDA to review each module separately, allowing the applicant to receive timely feedback and potentially resolve any deficiencies earlier in the review process compared to a traditional HDE application. Upon receipt of the final module, the FDA will make a filing decision that, if positive, triggers the HDE 75-day review clock for an approval decision.
Regulatory	HDE Filing	Humanitarian device exemption (HDE) application filing to the FDA. An HDE is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market.
Regulatory	HDE Supplemental Approval	An approval for a Humanitarian device exemption (HDE) as a supplemental indication
Regulatory	HDE Supplemental Filing	A filing for a supplemental Humanitarian device exemption (HDE) application
Regulatory	Humanitarian Use Device (HUD)	Filing Before submitting an HDE application to FDA, an HDE applicant must first prepare and submit a HUD designation request to OOPD and receive HUD designation.
Regulatory	Humanitarian Use Device (HUD) Designation	After receiving HUD designation, the HDE applicant may submit an HDE application to the appropriate assigned center (CDRH or CBER).
Regulatory	IDE Approval Decision	An approval of an investigational device exemption (IDE) allows for an investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a Premarket Approval (PMA). Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. An IDE in the device space is similar to an Investigational New Drug (IND) application in the drug space in that it allows for the initiation human clinical trials.
Regulatory	IDE Clinical Hold	“Clinical hold” when, among other reasons established by regulation, the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation.

Regulatory	IDE Conditional Approval	If FDA approves an IDE application with conditions, the sponsor may begin subject enrollment upon receipt of IRB approval and in accordance with the limits described in FDA's decision letter, including the maximum numbers of U.S. subjects and investigational sites, and must submit information addressing the issues identified as conditions of approval in FDA's letter within 45 days
Regulatory	IDE Request for Additional Information	FDA requires additional information to be submitted before making a decision on the IDE application.
Regulatory	IDE Submission	Company submits IDE, which if approved, allows the initiation of subject enrollment in a clinical investigation of a significant risk device.
Regulatory	IDE Withdrawal	Company withdraws IDE application
Regulatory	Medical Device Dispute Resolution Panel (MDDRP) Decision	The MDDRP provides advice to the Commissioner of the U.S. Food and Drug Administration (FDA) on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, significant regulatory decisions and actions by the FDA, and Agency guidance and policies. The Panel is convened infrequently and makes recommendations on issues that are lacking resolution.
Regulatory	Meeting with FDA	Any meeting occurring with the FDA
Regulatory	PMA Approval	Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. A Premarket Approval (PMA) differs from a 510(k) clearance in that it is much more of a stringent application process requiring sufficient evidence from the applicant that the device is safe and effective. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer, sometimes taking several years to obtain approval.
Regulatory	PMA Filing	Company files a Premarket Approval Application (PMA) to the FDA. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to begin an indepth review. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed. The letter will include the PMA reference number and the date FDA filed the PMA. Expedited review status, if appropriate, may be communicated at this time. The date of filing is the date that a PMA accepted for filing was received by the agency. The 180day period for review of a PMA starts on the date of filing.
Regulatory	Device Filing (Japan)	The Pharmaceuticals and Medical Devices Agency (PMDA) is the regulatory body in Japan which controls the marketing of medical devices. The regulatory pathway for "highly controlled medical devices" requires the submission of a Premarket Approval Application with the PMDA, a review, and approval before a device can be brought to market.

Regulatory	PMA Filing Not Accepted	The FDA will refuse to file the application for substantive review if a PMA application does not meet a minimum threshold of acceptability. If the information or data are presented unclearly or incompletely or are not capable of withstanding rigorous scientific review, FDA may consider the PMA incomplete and not file it. If FDA refuses to file a PMA, FDA will notify the applicant of the reasons for the refusal. This notice will identify the deficiencies in the application that prevent filing and will include the PMA reference number. FDA will advise the manufacturer of what information must be provided, or steps to be taken, to make the application fileable. The applicant can comply the the FDA's requests and resubmit the PMA or may request in writing within 10 working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Director of the Office of Device Evaluation to review FDA`s decision not to file the PMA.
Regulatory	PMA Modular Filing	In a Modular PMA the complete contents of a PMA are broken down into well delineated components (or module) and each component is submitted to FDA as soon as the applicant has completed the module, compiling a complete PMA over time. The PMA is viewed as a compilation of sections or "modules," such as preclinical, clinical, manufacturing, that together become a complete application. This method is recommended for products that are in early stages of clinical study. This method is not appropriate when the applicant is very close to being ready to submit a PMA or when the device design is in a state of flux or likely to change.
Regulatory	PMA Modular Filing Completed	The process begins with a PMA Shell which lays out the plan for submission of the modules. The shell is an outline of modules and identifies information necessary to support the filing and approval of a specific Class III product through a combined IDEPMA process. The review team will work with applicants to develop a customized shell for each specific product that includes module contents and suggested timelines. It is developed individually with the manufacturer for a specific device.
Regulatory	PMA Non-Approvable Decision	The FDA will send the applicant a not approvable letter if FDA believes that the application may not be or if the FDA is unable to reach an approvable decision due to a lack of significant information in the application. The not approvable letter will describe the deficiencies in the application, including each applicable ground for denial. When practical, FDA will identify what is necessary to make the PMA approvable. In response to a not approvable letter, the applicant may amend the PMA as requested, consider the not approvable letter to be a denial of approval of the PMA and request administrative review, or withdraw the PMA.
Regulatory	PMA Supplemental Approval	A PMA supplement approval is the FDA approval of the submission required for a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA; additional information provided to FDA for PMA supplement under review are amendments to a supplement
Regulatory	PMA Supplemental Filing	A PMA supplement filing is the submission required for a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA; additional information provided to FDA for PMA supplement under review are amendments to a supplement

Regulatory	PMA Tenative Approval	A provisional approval Premarket Approval Application (PMA). The "tentative" approval signifies that the product meets all safety, efficacy, and manufacturing quality standards for marketing in the U.S., and, but for the legal market protection, it would be on the U.S. market.
Regulatory	Pre-IDE/Pre-Submission	A company can submit pre-submission documents, previously known as the pre-IDE program, to the FDA for feedback regarding potential or planned medical device IDE or other premarket submissions, such as PMA, HDE, de novo, 510(k), or CLIA submissions. The guidance provides information regarding the logistics for submission, receipt, tracking, and review of/response to these requests.
Regulatory	Pre-IDE/Pre-Submission FDA Response	FDA Response In order to facilitate the initiation of clinical trials under the IDE regulation, the Food and Drug Administration (FDA) encourages sponsors to begin communicating with the ODE reviewing division prior to the submission of the original IDE application. This communication may take the form of a “PreIDE” meeting and/or a “PreIDE” submission.
Regulatory	Progress Update	Any regulatory update that does not fall into any other specified event types
Regulatory	Regulatory	Any interaction between company and regulatory body (typically FDA or EMA) that does not fall into any other specified event type
Regulatory	Regulatory (Emerging Markets)	Any interaction between company and regulatory body in a nonmajor market (i.e. BRIC, etc.) that does not fall into any other specified event type
Regulatory	Treatment Guidelines Announcement	Sometimes issued by company or association/organization related to indication, relating to changes in treatment recommendations or instructions
Regulatory	Withdrawal from Market	FDA encouraged or forced withdrawal from market
Regulatory	Withdrawal from Market (Emerging Markets)	Regulatory body encouraged or forced withdrawal from market; specifically for nonmajor markets (i.e. BRIC, etc.)
Reimbursement	Individual Country (Emerging Market) - Negative Recommendation	Specific Emerging Market country health care organization or private insurer deciding to not cover a drug’s costs, or if already reimbursed, a decision to limit or restrict the indication(s) or circumstances paid for
Reimbursement	Individual Country (Emerging Market) - Positive Recommendation	Specific Emerging Market Country health care organization or private insurer deciding to pay for a drug’s costs, in part or in full.
Reimbursement	Individual Country (Europe) - Negative Recommendation	Any European Country (excluding the UK’s NICE) national health insurance deciding not to cover a drug’s cost, or limiting/reducing the reimbursement previously allotted (e.g. IQWIG, SMC, AWMSG)
Reimbursement	Individual Country (Europe) - Positive Recommendation	Any European Country (excluding the UK’s NICE) national health insurance deciding to cover a drug’s cost, or expand the reimbursement previously allotted (e.g. IQWIG, SMC, AWMSG)

Reimbursement	Individual Country (Other) - Negative Recommendation	A non-EU and Non-Emerging Market country's health insurer or private payer deciding to not reimburse a drug's cost, or limit/reduce the previously stated reimbursement (e.g. Canada, Australia, etc.)
Reimbursement	Individual Country (Other) - Positive Recommendation	A non-EU and Non-Emerging Market country's health insurer or private payer deciding to reimburse a drug's cost, or expand the previously stated reimbursement (e.g. Canada, Australia, etc.)
Reimbursement	Japan - Negative Recommendation	Japan's health insurance agencies deciding not to reimburse a drug's costs, or limiting/reducing the previously stated reimbursement. Includes a decision by Japan's Central Social Insurance Medical Council (Chuikyo), being removed to NHI price listing, an assessment by PMDA
Reimbursement	Japan - Positive Recommendation	Japan's health insurance agencies deciding to reimburse a drug's cost, or expand the already allotted reimbursement (e.g. Added to NHI price listing)
Reimbursement	Medicare/Payer (US) Decision - Negative	Medicare, large private health insurance payer (Aetna etc.) or other payment agency or body in the U.S. (VA Hospitals VANF) deciding to not reimburse a drug's care, or reduce the previously allotted amount for reimbursement
Reimbursement	Medicare/Payer (US) Decision - Positive	Medicare, large private health insurance payer (Aetna etc.) or other payment agency or body in the U.S. (VA Hospitals) deciding to reimburse a drugs care, or expand the indication/increase the reimbursement from the previously allotted amount. Receiving a Jcode or QCode for payment reimbursement falls under this category as well.
Reimbursement	NICE (UK) Guidance - Negative	National Institute for Clinical Excellence (NICE), the U.K. health care agency, deciding not to reimburse a drug's costs. This includes draft guidance or final decision.
Reimbursement	NICE (UK) Guidance - Positive	National Institute for Clinical Excellence (NICE), the U.K. health care agency, deciding to reimburse a drug's costs. This includes draft guidance or final decision.
Reimbursement	Progress Update	Anything related to a decision being made by a health care insurer or government agency that is not a positive or negative decision. This could include a Medicare proceeding on reimbursement, a statement that a payer will reexamine a decision or any other nondeciding reimbursement event
Related Drug	Related Drug - Approval (US)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Related Drug	Related Drug - Approval (Japan)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Related Drug	Related Drug - Approval (EU)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Related Drug	Related Drug - Approval (EU) - Individual Country	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Related Drug	Related Drug - Approval (Emerging Markets)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Related Drug	Related Drug - Approval (Canada)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)

Related Drug	Related Drug - Approval (Australia/New Zealand)	When a drug/device combination product is approved as a drug but MDT maintains a device profile for the device portion of the combination product. (usually CDx or DDT)
Trial Announcement	Clinical Hold	Order issued by FDA to company to delay a proposed clinical investigation (subjects may not be given investigational device) or to suspend an ongoing investigation (no new subjects may be recruited and administered investigational device/patients already in study should be taken off therapy involving investigational device) unless specifically permitted by FDA in the interest of patient safety
Trial Announcement	Clinical Hold Lifted	Issued by FDA when grounds for hold no longer apply
Trial Announcement	Data Monitoring Board Analysis	Interim analyses of trial data conducted by medical, surgical and statistical experts selected by company to serve as an independent monitoring board, will make recommendations to continue or stop trial
Trial Announcement	Expanded Access Program	Designed to make products available as early in the device evaluation process as possible to patients without therapeutic options, either because they have exhausted or are intolerant of approved therapies
Trial Announcement	First-in-Human Implant	Used when a company announced it has performed an implant of a device (ie. stent, scaffold, valve, etc.) for the first time in humans.
Trial Announcement	Initiation	Company issues press release announcing first patient has actually been enrolled or treated in trial, also used to distinguish between Trial Announcement event so that events do not repeat each other
Trial Announcement	Initiation (Emerging Markets)	Company issues press release announcing first patient has actually been enrolled or dosed in trial that is being conducted in a nonmajor markets (i.e. BRIC, etc.), also used to distinguish between Trial Announcement event so that events do not repeat each other
Trial Announcement	Partial Hold	Order issued by FDA to company to delay a proposed clinical investigation (subjects may not be given investigational device) or to suspend an ongoing investigation (no new subjects may be recruited and administered investigational device/patients already in study should be taken off therapy involving investigational device) unless specifically permitted by FDA in the interest of patient safety
Trial Announcement	Partial Hold Lifted	Issued by FDA when grounds for partial hold no longer apply
Trial Announcement	Patient Enrollment Completed	Enrollment target reached or specific update relating to patient enrollment progress in trial
Trial Announcement	Patient Enrollment Completed (Emerging Markets)	Enrollment target reached or specific update relating to patient enrollment progress in trial that is being conducted in a nonmajor market (i.e. BRIC, etc.)
Trial Announcement	Protocol Amendment	Any changes to design of trial, must be approved by appropriate regulatory agency (depending on country)
Trial Announcement	Regulatory Approval to Initiate	Permission from any regulatory agency (FDA/EMA/etc) for clinical trial to initiate in given country

Trial Announcement	Trial Announcement	Company announces plans to initiate a new study
Trial Announcement	Trial Announcement (Emerging Markets)	Company announces plans to initiate a new study in any emerging market
Trial Announcement	Trial Completed	All patients in trial have completed the trial
Trial Announcement	Trial Completed (Emerging Markets)	All patients in a trial in a nonmajor market (i.e. BRIC, etc.) have completed the trial, including followup
Trial Announcement	Trial/Enrollment Reinitiated	Enrollment reinitiated after trial placed on clinical hold or enrollment suspended for various reasons
Trial Announcement	Trial/Enrollment Suspension	Company stops enrollment in clinical trial
Trial Announcement	Trial Progressing	Trial continues to enroll patients, trial is ongoing, basic trial update
Trial Announcement	Trial Progressing (Emerging Markets)	Trial continues to enroll patients, trial is ongoing, basic trial update for a trial being conducted in nonmajor markets (i.e. BRIC, etc.)
Trial Data	Final Results	Can be explicitly stated as “final analysis” of data
Trial Data	Preclinical Results	Data from in vitro or animal laboratory studies
Trial Data	Published Results	Any data that is published in a journal or publication
Trial Data	Retrospective Analysis	Can include posthoc analysis or pooled data
Trial Data	Subgroup Analysis	Data from subgroup of original trial patient population
Trial Data	Suspension	Can include data where endpoints are not reached or lack of statistical significance, causes company to terminate development of device
Trial Data	Top-Line Results	First mention of clinical efficacy data, falls under “interim analysis”
Trial Data	Trial Data	Can include preliminary observations or safety data; typically not a full analysis
Trial Data	Trial Data (Emerging Markets)	Any data for a trial that is being conducted in a nonmajor market (i.e. BRIC, etc.)
Trial Data	Updated Results	Updated clinical data from topline, also falls under “interim analysis”, can include more patients, longer treatment, followup, etc.