Finding Medical Device and Drug Approval Information Through the Food and Drug Administration Databases

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SUMMARY

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Finding Medical Device and Drug Approval Information Through the Food and Drug Administration Databases

The U.S. Food and Drug Administration (FDA) maintains a variety of publicly available databases containing information vital to the agency's regulatory oversight of the medical device and pharmaceutical industries. The data compiled in these databases are acquired through legal reporting requirements set forth by laws including the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA). Additionally, data can be acquired by the agency pursuant to various regulatory requirements for devices and drugs.

Congressional staff may consult the FDA's catalog of databases to identify information on a medical device or drug's current status in the United States. The data collected in these databases can be helpful in a variety of efforts, including tracking compliance with current FDA regulations, determining the regulatory status of a particular product, and monitoring notification of product shortage or recall.

Since there is not a single, searchable platform on the FDA's website that allows users to search across the agency's entire catalog of databases, this report provides information on several frequently consulted FDA medical device and drug databases. The report is intended to provide an overview of select databases to help users understand the types of information available; it is not a comprehensive listing of all current FDA databases. For each database included, CRS provides information on how to access the database, the types of data in the database, and each database's currency. Data availability and accessibility will vary depending on the scope, types of data, search capabilities, and terminology used by each individual database.

This report also provides an overview of the FDA centers responsible for regulating medical device and drug products, brief summaries of the FDA's approval processes for medical devices and drugs, references to additional CRS products on the FDA's regulation of these products, and a glossary of terms.

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Purpose and Scope

The U.S. Food and Drug Administration (FDA) maintains a variety of publicly available databases containing information vital to the agency's regulatory oversight of the medical device and pharmaceutical industries. The data compiled in these databases are acquired by the FDA through legal reporting requirements set forth by laws including the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA). Additionally, data may be acquired by the FDA pursuant to various regulatory requirements for devices and drugs.[1]

These databases allow public users from sectors including industry, government, public stakeholders, and academia to freely access data collected and maintained by the agency. The variety of data maintained in the FDA databases is broad, from the current status of product availability in the United States to the number of recorded adverse reactions reported to the agency.

Congressional staff may need to consult the FDA's collection of databases in order to identify information related to medical products, including

- current product availability (e.g., in shortage),
- current FDA device and drug marketing status,[2]
- current FDA device classification,
- adverse event(s) reporting, and
- manufacturer (including contact information).

There is not a single, searchable platform on the FDA's website that allows users to search across the agency's entire catalog of databases. The databases often contain both unique and overlapping information. Users may need to use multiple databases depending on the information needed. Relevant data are also presented in a variety of formats on the FDA's website. For example, some data are accessible through interactive tables (e.g., *Drug Recalls*), while other data are housed in standalone databases on the website https://www.accessdata.fda.gov/. For the purpose of this report, all data repositories on the FDA's website will be referred to as a *database*.

This report provides examples and is not a comprehensive listing of all FDA databases. The data's availability and accessibility will vary depending on the scope, types of data, search capabilities, and terminology used in the individual database. The report includes a direct link to each database, the types of data maintained in the database, and the database's frequency of update. The information provided for each database is not exhaustive and is meant only to illustrate its available content.

Finally, while the phrases *premarket* and *postmarket data* are used throughout this report, it is important to note that, in general, data for products currently undergoing FDA review are not available publicly through the FDA's website.[3] The information used to populate these databases is obtained through premarket submissions publicly released after FDA marketing authorization is granted (where applicable; many medical devices are not subject to premarket review

[1] Regulations promulgated pursuant to these statutory requirements are generally found in the *Code of Federal Regulations* (C.F.R.), Title 21—Food and Drugs.

[2] Marketing status indicates how a product is sold in the United States (e.g., prescription, over-the-counter).

[3] FDA is restricted by regulation as to what it may publicly disclose with respect to commercial confidential information (CCI). See 21 C.F.R. §807.95.

requirements). To obtain data for products currently under FDA review, CRS recommends contacting the FDA congressional liaison.[4]

For definitions of terms used throughout this report, see the **Appendix.**

FDA Regulation of Drugs and Medical Devices

The FDA, within the Department of Health and Human Services (HHS), is the federal agency responsible for the safety, efficacy, and security of medical products, including human drugs, biological products, medical devices, and radiation emitting products in the United States.[5] Under most circumstances, drugs, devices, and biologics may be marketed in the United States only if they have been approved, cleared, or licensed by FDA.[6] In the premarket approval phase, the FDA reviews manufacturers' applications to market drugs or devices in the United States. Once the product is on the market, FDA continues its oversight of safety and effectiveness. The postmarket approval phase lasts as long as the item is in the market.[7]

In general, drugs and devices are approved or cleared under the FFDCA,[8] whereas biologics are licensed under the PHSA.[9] For further information related to the FDA's approval and regulation processes of drugs and medical devices, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, and CRS Report R47374, *FDA Regulation of Medical Devices*. In addition, the CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, broadly summarizes selected differences in statutory requirements among drugs, biologics, and devices.

The FDA consists of nine center-level organizations and 13 headquarter (HQ) offices.[10] Within the FDA, the following centers oversee drugs, biologics, and devices:

- Center for Biologics Evaluation and Research (CBER) oversees certain biologics (e.g., vaccines and gene therapies).
- Center for Drug Evaluation and Research (CDER) oversees chemical drugs and some therapeutic biologics.[11]

[4] CRS Report 98-446, *Congressional Liaison Offices of Selected Federal Agencies*, by Audrey Celeste Crane-Hirsch.

[5] FDA, *What We Do*, https://www.fda.gov/about-fda/what-we-do.

[6] Within the *Code of Federal Regulations*, see for drugs, 21 C.F.R. §314; for devices, see 21 C.F.R. Part 807, Subpart E (510(k) clearance); 21 C.F.R. Part 814 (Premarket Approval); 21 C.F.R. Part 860, Subpart D (De Novo Request for Classification). Biological products are licensed under Section 351 of the PHSA; some therapeutic protein products are approved under Section 505 of the FFDCA.

[7] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Hassan Z. Sheikh.

[8] CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

[9] Certain biological products, such as hormonal products, are regulated under FFDCA For more information, see FDA, *Frequently Asked Questions About Therapeutic Biological Products*, https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products.

[10] FDA, *FDA Organizations Chart*, https://www.fda.gov/about-fda/fda-organization/fda-organization-charts.

[11] For more information on the categories of therapeutic biological products regulated by CDER (under the FFDCA and/or the PHSA, as appropriate), see FDA, *Frequently Asked Questions About Therapeutic Biological Products*, https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products.

- Center for Devices and Radiological Health (CDRH) oversees medical devices and radiologic products.[12]

These centers are responsible for maintaining the publicly available databases on the FDA's website corresponding with their industries of oversight. **Table 1** lists the databases included in this report, with the center(s) responsible for each database's maintenance. Given that some centers may have overlapping authority over certain medical products (e.g., combination products-therapeutic or diagnostic products that combine drugs, biologics, and devices),[13] some databases appear in multiple columns.

Table 1. Databases Maintained by FDA Centers

The following table provides a list of select FDA databases organized by the FDA centers responsible for maintaining these databases.

CBER	CDER	CDRH
• Database of Licensed Biological Products (Purple Book)[a] • Device Classification Under Section 513(f)(2) (De Novo)[b] • FDA Adverse Event Reporting System (FAERS) public dashboard[c] • CBER-Regulated Products Shortages • Drug Recalls[c] • Postmarket Requirements and Commitments database[c]	• Drugs@FDA • Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) • Database of Licensed Biological Products (Purple Book)[a] • Approved Risk Evaluation and Mitigation Strategies (REMS) • Postmarket Requirements and Commitments database[c] • Drug Establishments Current Registration Site • FDA Adverse Event Reporting System (FAERS) public dashboard[c] • FDA Drug Shortages • Drug Recalls[c]	• Establishment Registration & Listing • Devices@FDA • Product Classification Database • Device Classification Under Section 513(f)(2) (De Novo)[b] • Premarket Approvals (PMA) • 510(k) Premarket Notification • Over the Counter (OTC) Database • CLIA - Clinical Laboratory Improvement Amendments • MAUDE (Manufacturer and User Facility Device Experience) • Post-Approval Studies (PAS) Database • Total Product Life Cycle (TPLC)

Source: Compiled by CRS based on information from FDA.gov.

a. Contains information about all FDA-licensed biological products regulated by CDER and information on all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by CBER.

b. Allows user to narrow search by FDA Center (e.g., CBER or CDRH).

c. Contain data from both CBER and CDER.

[12] CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

[13] CRS Report R47374, *FDA Regulation of Medical Devices*, by Amanda K. Sarata.

Medical Devices Databases

The CDRH regulates firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States.[14] Additionally, CDRH regulates radiation-emitting electronic products (medical and nonmedical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens, and color televisions. Medical devices are regulated based on the risk posed to the consumer and are classified into the following categories.

- Class I medical devices are considered low risk. As such, general controls are considered sufficient to provide reasonable assurance of safety and effectiveness.[15]
- Class II medical devices are considered moderate risk; therefore, general and special controls are considered to provide reasonable assurance of safety and effectiveness.[16]
- Class III medical devices are considered high risk; therefore, they are subject to general controls and the PMA process to provide reasonable assurance of safety and effectiveness.[17]

Unless specifically excluded by regulation, all devices must meet general controls. These include both premarket and postmarket requirements. General controls include 510(k) premarket notification,[18] registration, listing, and compliance with current good manufacturing practices as set forth in FDA's quality system regulations.[19] CRS Report R47374, *FDA Regulation of Medical Devices*, provides further information on the FDA device classification processes and device regulatory controls.

Once a device is approved, the FDA has the authority to require product sponsors to perform a post-approval study (or studies). These can occur at various stages, including the time of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, health care professionals, the device industry, the FDA, and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices.[20]

FDA databases include information associated with a specific medical device, such as the name of a product's manufacturer, the device's current FDA classification, when the item was authorized for marketing by the FDA, or if adverse events with a device have been reported to the FDA.

Table 2 provides select information for several FDA databases containing medical device data. For each entry, the table lists the circumstance in which a user might consult that database. Because terminology used by the FDA across the databases is not consistent, the table defines what types of data each column encompasses.

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[14] CRS Report R47374, *FDA Regulation of Medical Devices*, by Amanda K. Sarata.

[15] FFDCA §513(a)(1)(A); 21 U.S.C. §360c(a)(1)(A).

[16] FFDCA §513(a)(1)(B); 21 U.S.C. §360c(a)(1)(B).

[17] FFDCA §513(a)(1)(C); 21 U.S.C. §360c(a)(1)(C).

[18] 21 C.F.R. §807.92.

[19] CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

[20] FDA, *Post-Approval Studies (PAS) Database*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

- **Proprietary Name:** Name of device on record with the FDA. May also be listed as *Device Name* in select databases.
- **Decision Date:** Date of approval on record with the FDA. May be referred to as *Approval Date* in select databases.
- **Contact**: This information may be recorded as the *Applicant, Correspondent, Owner/Operator,* or *Manufacturer* on file with the FDA.
- **Class:** Medical device classification assigned by the FDA. Device may be considered *Class I, Class II*, or *Class III*.
- **510(k) Number:** A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, or is substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).[21]
- **Regulation Number:** A device's regulation number in the *Code of Federal Regulations*. If the database does not reference a regulation number, the device has not yet been classified and the device class listed (1, 2, or 3) is proposed, not final.

[21] 21 C.F.R. §807.92; FDA, *Device Approvals and Clearances*, https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-and-clearances.

Table 2. Medical Devices Databases

("+" indicates that types of data are included in database; "—" indicates that types of data are not included in database. Click on each database to navigate to the site.)

Database[a] *Example of database content and when to consult.*	**Data**						**Updated**
	Proprietary Name	**Decision Date**	**Contact**	**Class**	**510(k) Number**	**Regulation Number**	
Establishment Registration and Listing[b] *What company manufactures this device?* *Which devices are made by this manufacturer?*	+	—	+	+	+[c]	+	Weekly
Devices@FDA *Is this device FDA approved or cleared?*	+	+	+	—	+	+	Weekly
Product Classification Database *What is this device's FDA classification?*	—	—	—	+	—[d]	+	Weekly
510(k) Premarket Notification *Is this device cleared?*	+	+	+	—	+	+	Weekly
Device Classification Under Section 513(f)(2) (De Novo)[e] *Does this device have a De Novo number?*	+	+	+	—	—	+	Weekly
Premarket Approval (PMA) *When was this Class III device approved?*	+	+	+	—	—	—	Weekly

Database[a] *Example of database content and when to consult.*	Data						Updated
	Proprietary Name	**Decision Date**	**Contact**	**Class**	**510(k) Number**	**Regulation Number**	
Over the Counter (OTC) Database *Who manufacturers this OTC test?*	+	+	+	—	+	+	Weekly
Clinical Laboratory Improvement Amendments (CLIA)[f] *What is the CLIA categorization for the test system?* *What analyte does the test system detect?*	+	+	+	—	+	+	Weekly
Manufacturer and User Facility Device Experience (MAUDE) *Are there adverse events reported for this device?*	+	—	—[g]	—	—	—	Weekly
Post-Approval Studies (PAS) Database *Were there PAS required for this device?*	+	+	+	—	—	—	Weekly
Total Product Life Cycle (TPLC) *Are there any postmarket FDA actions associated with this device?*	+	—	—[h]	+	—	+	Weekly

Source: Compiled by CRS based on information from FDA.gov.

a. Database name in bold.

b. Registration and Listing does not denote approval or clearance of a firm or their device(s) by the FDA.

c. Premarket Submission Number (if available).

d. *Submission Type* will note 510(k) submission, if applicable.

e. De Novo Classification is an alternate pathway to reclassify new medical devices automatically placed in class III after receiving a Not Substantially Equivalent (NSE) determination in response to a 510(k) submission (21 C.F.R. §860.200). Amended by Section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), to provide a second pathway allowing a sponsor to submit a de novo classification request to the FDA without first being required to submit a 510(k).

f. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 U.S.C. §263a; PHSA §353) and the associated regulations (42 C.F.R. §493) provide the authority for certification and oversight of clinical laboratories and laboratory testing.

g. Manufacturer name is listed but does not include contact information in the entry.

h. Manufacturer name may be listed but does not include contact information in the entry.

Drugs and Biologics Databases

To market a new prescription brand-name or generic drug for use in humans in the United States, the sponsor (generally the drug manufacturer) must submit a new drug application (NDA) to the FDA, demonstrating that the drug is safe and effective for its proposed use. Drugs are approved via an NDA under Section 505 of the FFDCA, and biologics are licensed via a biologics license application (BLA) under Section 351 of the PHSA. For generic drug products, the manufacturer can submit to FDA an abbreviated NDA (ANDA) demonstrating that the generic product is the same as the brand-name drug.[22]

For NDAs, once the required materials are submitted by the sponsor, they are reviewed by CDER physicians, statisticians, chemists, pharmacologists, and other scientists. This group also reviews the sponsor's proposed labeling.[23]

In general, the requirements and review pathway for BLAs are similar to the requirements and review pathway for NDAs. The product sponsor must demonstrate that the biologic and the facilities and processes for manufacturing the product are safe, pure, and potent (i.e., effective). Biologics are subject to certain FFDCA provisions (e.g., Risk Evaluation and Mitigation Strategies).[24]

For both drugs and biologics, manufacturers must report all serious and unexpected adverse events to FDA within 15 days of becoming aware of them.[25] Clinicians and patients may report adverse events to the agency at any time. Once a drug is on the market, FDA can require the manufacturer to conduct additional studies or clinical trials based on newly acquired information, and can require labeling changes based on information it gathers from mandatory and voluntary adverse event reports.[26]

Table 3 provides select information for several FDA databases containing drug data maintained by CBER and CDER.[27] For each entry, **Table 3** lists the circumstance in which a user might consult that database. Because terminology used by the FDA across the databases is not consistent, below CRS defines what types of data each column encompasses.

- **Proprietary Name:** Name on record with the FDA. May also listed as *Trade Name* or *Drug Name.*
- **Availability:** May indicate if the item is available over the counter (OTC), discontinued, recalled, or in shortage. May be referred to as *Marketing Status.*
- **Contact:** Includes applicant, correspondent, or manufacturer on file with the FDA.
- **Approval Date:** May be referred to as *Decision Date.*

[22] CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Hassan Z. Sheikh.

[23] For more information on the NDA process, see FDA, *New Drug Application*, https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

[24] For more information on the BLA Process, see FDA, *Biologics License Applications (BLA) Process (CBER)*, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

[25] 21 C.F.R. §314.80; 21 C.F.R. §600.80(c).

[26] 21 U.S.C. §355.

[27] See **Table 1.**

- **Dosage Form:** The physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable.
- **Label:** The FDA-approved label is the official description of a drug product that includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.
- **Active Ingredient:** The drug component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

This table denotes the shortage and recall databases, given current congressional interest in the availability of these products.

Table 3. Drugs and Biologics Databases

("+" indicates that types of data are included in database; "—" indicates that types of data are not included in database. Click on each database to navigate to the site.)

Database[a] *Example of database content and when to consult*	Data							Updated
	Proprietary Name	**Availability**	**Contact**	**Approval Date**	**Dosage Form**	**Label[b]**	**Active Ingredient**	
Drugs@FDA *Is this drug FDA approved?*	+	+	+[c]	+	+	+	+	Daily
Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) *Is this drug available in the U.S.?*	+	+	+[d]	+	+	—	+	Monthly
Database of Licensed Biological Products (Purple Book) *Is this biologic FDA approved?*	+	+	+	+	+	+	+	Monthly
Approved Risk Evaluation and Mitigation Strategies (REMS)[e] *Is this drug in the REMS program?*	+	—	—	—[f]	+	—	+	As needed
Drug Establishments Current Registration Site *Where is a drug manufacturer located?*	—	—	+	—	—	—	—	Daily
FDA Adverse Event Reporting System (FAERS) Public Dashboard *Are there adverse reactions associated with this drug?*	+	—	—	—	—	—	—	Quarterly
Postmarket Requirements and Commitments *Are there statutory requirements associated with this product?*	+	—	+[g]	+	—	—	+	Quarterly

Database[a] *Example of database content and when to consult*	Data							Updated
	Proprietary Name	**Availability**	**Contact**	**Approval Date**	**Dosage Form**	**Label[b]**	**Active Ingredient**	
Drug Shortages and Recalls								
FDA Drug Shortages *Is this drug currently in shortage?*	+	+	+	—	+	—	+	Updated daily
CBER-Regulated Products Shortages *Is this CBER regulated product in shortage?*	+	+	+	—	+	—	—	As needed.
Drug Recalls *Has the manufacturer recalled this drug?*	+	+	+[c]	—	+	—	—	Weekly

Source: Compiled by CRS based on information from FDA.gov.

a. Database name in bold.

b. Also see *FDA Label Search* database, https://labels.fda.gov/proprietaryname.cfm.

c. Company name is listed but does not include contact information in the entry.

d. Applicant Holder is listed but does not include contact information in the entry.

e. Also see the *REMS Public Dashboard*, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/risk-evaluation-and-mitigation-strategy-rems-public-dashboard.

f. REMS approval date.

g. Applicant name is listed but does not include contact information in the entry.

Additional CRS Resources

- CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*
- CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*
- CRS Report R47374, *FDA Regulation of Medical Devices*
- CRS In Focus IF11379, *Medical Product Innovation and Regulation: Benefits and Risks*
- CRS In Focus IF11389, *FDA Regulation of Laboratory-Developed Tests (LDTs)*
- CRS Report R46985, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress*
- CRS In Focus IF11058, *Drug Shortages: Causes, FDA Authority, and Policy Options*

Appendix. Glossary

- **Applicant.** Manufacturer or sponsor submitting required paperwork to FDA.
- **Approved Risk Evaluation and Mitigation Strategies (REMS).** 21 U.S.C. §355-1 establishes FDA's REMS authority. A REMS is a required risk management strategy that can include one or more elements to ensure that the benefits of a drug outweigh its risks.
- **De Novo Classification.** An alternate pathway to reclassify new moderate- or low-risk medical devices automatically placed in Class III to either Class I or Class II after receiving a not substantially equivalent (NSE) determination in response to a 510(k) submission. The Food and Drug Administration Safety and Innovation Act (FDASIA) provided a second pathway allowing a sponsor to submit a de novo classification request to the FDA without first being required to submit a 510(k). If the classification request is approved, FDA grants the device-marketing authorization and creates a new generic device type, allowing the device to serve as a predicate device for 510(k) submissions in the future (21 C.F.R. §860.200).
- **Humanitarian Use Device (HUD).** A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (21 USC §360j(m)).
- **Humanitarian Device Exemption (HDE).** A marketing application for an HUD; it is exempt from the effectiveness requirements of Sections 514 and 515 of the FFDCA and is subject to certain profit and use restrictions.
- **Marketing Status.** Indicates how a product is sold in the United States.
- **Postmarket Requirements and Commitments.** Refers to studies and clinical trials that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use.
- **Premarket Approval (PMA).** FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices, which are medical devices 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 (21 C.F.R. §814). If successful, this results in an *approval*.
- **Premarket Notification 510(k).** A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, or is substantially equivalent, to a legally marketed device not subject to premarket approval (21 C.F.R. §807 Subpart E). If successful, this results in a *clearance.*
- **Product Development Protocol.** In the product development protocol (PDP) method for gaining marketing approval, the clinical evaluation of a device and the development of necessary information for marketing approval are merged into one regulatory mechanism.[28] A Class III device for which a PDP has been declared completed by FDA under will be considered to have an approved PMA (21 C.F.R. §814.19).

[28] FDA, *PMA Application Methods*, https://www.fda.gov/medical-devices/premarket-approval-pma/pma-application-methods.

- **Sponsor (Drug).** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators (21 C.F.R. §312.3(b)).
- **Sponsor (Device).** A person who initiates, but who does not actually conduct, the investigation; that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators (21 C.F.R. §812.3(n)).

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