BACKGROUND

The first — and most basic — question is: Why do some products and services have to be regulated?

The Food and Drug Administration (FDA) was created to address health risks that began to emerge more than a century ago when the production of food and medical products became industrialized, and could no longer be controlled by individual consumers. This regulatory body is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safe, and affordable. The agency performs this task by allowing these regulated products to be marketed across the United States after they meet evidence-based, rigorously defined public health standards and requirements. Familiarity with FDA requirements is thus very important for any medical device innovator or firm that manufactures or plans to manufacture, sell, transport, or import any of the thousands of FDA regulated products.

A regulatory strategy is a formal document that aligns the regulatory activities to bring a new or modified product to market with the business strategy for that product. It provides overall definition and direction to the project team for the product being developed by identifying the important regulatory elements to be addressed to market the device.
WHERE DOES REGULATIVE STRATEGY FIT IN PRODUCT DEVELOPMENT?

In the forefront! Understanding relevant regulatory requirements is fundamental to successful commercialization, and must be a part of early product development planning. Early inclusion provides valuable input to the design of the device, risk assessment, testing, and labeling. A sound regulatory strategy will support alignment of the clinical development and evaluation plan with business objectives, and promotes the early detection and removal of barriers to achieving commercialization milestones.

The strategy can include information about the regulatory plan for the premarket regulatory submission, planned interactions with the regulatory authorities, and can be combined with clinical and reimbursement strategies. Regulatory strategies often provide inputs to the Quality Management System (QMS) such as post market surveillance/vigilance activities that promote timely regulatory compliance. Most importantly, a regulatory strategy that includes proactive and collaborative interaction with regulatory authorities is often a differentiating factor for bringing commercially successful and innovative products to market in today's competitive marketplace.

Regulatory requirements in the United States and the rest of the world are constantly evolving. Therefore, in order to avoid delays to market, reworking costs, and frustration of senior executives and investors, innovators must keep their finger on the regulatory pulse throughout the product development process.

FDA REGULATORY FRAMEWORK

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. It is also responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary exposure to radiation-emitting products. The FDA's regulatory framework for medical devices is a risk-based approach, whereby the regulation to which a device is subject varies considerably depending on the risks and technology associated with the device’s intended use, indications, and technological characteristics. The device classification defines the regulatory requirements for a general device type.

There are three classifications for Medical Devices: Class I, II, and III. Regulatory control increases from Class I to Class III. Devices that present relatively low risk are generally placed in Class I or Class II. Most Class I devices are subject to the lowest level of regulation, in which they must register their firm and list the device they sell while complying with Good Manufacturing Practices (GMP). Unless explicitly exempted, devices must establish their safety and effectiveness through the appropriate submission mechanism. In many cases this is when information submitted by the applicant establishes that the device is “substantially equivalent” to a similar legally marketed Class I or Class II device, called a “predicate”, in a 510(k) submission (see section below, Developing A Regulatory Strategy). Devices that do not qualify for 510(k) clearance are automatically designated as Class III, which is typically reserved for devices posing greatest risk (e.g., life-sustaining, life-supporting, implantable devices or devices that are not substantially equivalent to a predicate device). Most Class III devices are subject to a more involved process called a Premarket Approval, in which valid scientific and clinical evidence demonstrating reasonable assurance of safety and effectiveness must be submitted to support the device’s intended use. In cases where there is no suitable predicate and the device presents low to moderate risk, the developer may use the De Novo process to request reclassification to Class II.

PREMARKET NOTIFICATION OR 510(k) PATHWAY – 21 CFR PART 807 SUBPART E

Premarket notification is also referred to as 510(k) and is considered a marketing clearance application; therefore, the FDA “clears” 510(k)’s. The clearance is based on the determination of Substantial Equivalence. A 510(k) is typically required in three scenarios: 1) introducing a new device to the market for the first time; 2) changing the indications for use of a previously cleared device; and 3) making significant modifications to a previously cleared device. There are three types of 510(k) submissions:

1. Traditional 510(k) relies on demonstration of substantial equivalence, and can be used under any circumstance.
2. Abbreviated 510(k) can be used if certain criteria are met (must include elements of 21 CFR 807.87), requires that
A standard is a document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

FDA has issued a detailed framework to assist agency reviewers in determining whether a new device is “substantially equivalent” to a legally marketed predicate that may be cleared via 510(k) notification process. A device is substantially equivalent if, in comparison to a predicate it:

- **Has the same intended use as the predicate** - Intended use of a product is determined by the intent of the manufacturer, as evidenced by the product’s design and labeling. If the intended use differs, the reviewer’s analysis stops, and the device is deemed not substantially equivalent, thereby requiring pre-market approval (PMA). Generally, differences in the specific indication statements will not render a new device not substantially equivalent, provided that the differences do not raise different questions of safety or effectiveness as compared to the predicate. It should be noted that in evaluating the intended use and indications for use of predicate devices for substantial equivalence, only the claims that have been cleared by FDA are considered. Thus, although devices are commonly used beyond the scope of their cleared indications, these “off-label” uses are not to be considered by FDA in the substantial equivalence analysis.

- **Has the same technological characteristics** - such as design, materials, and energy source(s), as the predicate: If the characteristics are the same or very similar, the device may be found substantially equivalent. However, if there are new characteristics, the reviewer must ask whether they could affect safety or effectiveness. If the new technological characteristics raise new safety or effectiveness issues compared to the predicates, the device will be found not substantially equivalent. The device must have the same general intended use as a predicate to be considered substantially equivalent, it need not be labeled with exactly the same specific claims as the predicate device.

The FDA guidance indicates that the 510(k) regulatory standard does not permit the use of split predicates. A split predicate is where one predicate device is used to demonstrate the same intended use and another predicate device is used to demonstrate the same technological characteristics. When multiple predicates are cited, each identified predicate device must have the same intended use. Technological differences are allowed but only if they achieve the same intended use. Multiple predicates can be used when the submitter wants to combine features from multiple predicate devices without altering the (1) intended use and/or (2) risk profile relative to the predicate devices. When a manufacturer does identify multiple predicates, the primary predicate refers to the one with indications for use and technological characteristics most similar to the device under review. Although using a single predicate is optimal, when multiple predicates are appropriate (as described in the example below), FDA recommends identifying a primary predicate in the submission to facilitate a timely, well-supported decision.

**Example:** A manufacturer submits a 510(k) for a new hemodialysis catheter. This new catheter has an extension (the portion of the device outside the body) design that is similar to predicate A and a tip (the portion of the device inside the body) design similar to predicate B. Both predicates A and B have the same intended use as the new device. In
DE NOVO

If a device has no appropriate predicate, it will automatically be considered a Class III device. Under a statutory provision enacted in the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), it may be possible to obtain reclassification to Class II, thereby permitting 510(k) clearance for devices which are low to moderate risk. For such devices, FDA may change the classification of a device from Class III if it determines that general and special controls would provide reasonable assurance of the safety and effectiveness of the device. In this process, FDA creates a new regulation and product code to address the specific device type, and the device, once cleared through the de novo pathway becomes an appropriate predicate for clearance of other devices going forward.

According to the 2012 Food and Drug Administration Safety and Innovation Act (“FDASIA”), there are now two potential pathways for a company to seek de novo review of its medical device. The historical option is to first proceed through the 510(k) pathway, and when FDA finds that the device is not substantially equivalent to the predicates, the company has 30 days after the not substantially equivalent determination to submit a request for de novo review. Alternatively, a company can now also proceed using the direct de novo pathway. If the company determines there is no predicate upon which to base a determination of substantial equivalence, the company may submit a request for de novo review without first filing the 510(k) notice and waiting for FDA to issue an not substantially equivalent determination.

In practice, a de novo reclassification petition is typically filed only after a pre-submission meeting with FDA to discuss the appropriateness of the pathway and the data that will be necessary to support reclassification. Submissions utilizing the de novo pathway are typically supported by clinical data, and must also provide proposed “special controls” intended to regulate the product when it is reclassified to class II. Special controls include performance standards, post-market surveillance, patient registries, special labeling requirements, and premarket data requirements that are specific to this new class of devices. Once the device is reclassified to class II and cleared, the special controls document created will guide the data required for future submissions for these types of devices.

FDA aims to make a classification determination on the de novo petition by written order within 120 days of the request, although if the agency determines that necessary information is missing from the petition, FDA can place the submission on hold pending receipt of the information, and this hold will stop the review clock. If FDA grants the request for reclassification to Class II in the de novo petition, the device is permitted to enter commercial distribution in the same manner as if a 510(k) clearance had been granted for the device.

PREMARKET APPROVAL (PMA) – 21 CFR PART 812

Class III devices, or novel devices where the 510(k) pathway and de novo reclassification are not deemed appropriate, must be approved for market via the PMA pathway. This approval requires that the safety and effectiveness of the device be established with valid scientific evidence from high-quality clinical testing. PMA submissions are typically more extensive than those using the 510(k) pathway, although 510(k) pathways requiring clinical evidence can approximate the complexity of a PMA. Approval of a PMA also requires detailed information on the sponsor’s Quality Management Systems and a pre-approval inspection of the sponsor’s manufacturing facilities by FDA, neither of which is required for 510(k) clearance or de novo reclassification. Similarly, for a PMA with clinical evidence, a Bioresearch Monitoring (BIMO) inspection of the clinical sites and the sponsor’s clinical testing files is routinely required. The time frame for FDA review of PMA applications is considerably longer than review times for a routine 510(k) submission. Specifically, FDA has 180 days to perform its initial review of a PMA submission (compared to 90 days for a 510(k) notice). However,
FDA’s initial PMA review typically results in a “major deficiency letter,” which requests additional information from the sponsor and resets FDA’s review clock. From submission to ultimate approval of a PMA generally requires a minimum of 18 to 24 months.

**DEVELOPING A REGULATORY STRATEGY**

A strategy should start with the collaboration of a cross functional team to identify important questions about the product. The first step is to determine whether the product is or is not a medical device. The team should list all that is known or will be asked about the product such as: What is the device? How is it to be used? What markets will be served? Is this a new/novel product or is it a modification of an existing device? Are there similar devices being distributed? What claims will be made? Other considerations are the type of regulatory submission, device risks, and any lifecycle considerations. Regulatory strategies should be living documents that are reviewed and updated as the project evolves. The following is a guideline of things to consider for developing a regulatory strategy:

1. **Determine Indications for Use (IFU)**

   Determining the IFU is the first step in developing the regulatory strategy. The IFU is a basic description of the manner in which the device is intended to be used. The IFU should describe:
   - How the device is intended to be used – specify diagnostic purpose for which the safety and effectiveness of the device has been validated. (Ex. screening, real-time monitoring, etc.)
   - For whom the device is intended to be used – specify intended population (age, patient group, diagnoses type)
   - The setting/environment of intended use (ex. in home, under supervision of a health care professional, etc.)
   - If there are populations that should not use the device or potential differences in diversity, growth or development milestones.
   - Other information that may be included in the IFU –
     - Information the device reports
     - Organ or body system (s) examined or impacted (ex. brain, heart, etc)
     - Conditions under which the device will be used
     - Who will use the device (operator or target user)?
     - For what condition?
     - Therapeutic implications from device results
     - Is the device proposed for prescription or over-the-counter use?
     - Could the device qualify for expedited review or humanitarian use designation?

   The IFU has to be consistent with device output, how the device was used in validation studies, labeling claims and instructions.

2. **Device Classification and Product Code**

   The determination of a device’s regulatory classification is typically made based on comparison to current classification regulations and legally marketed devices. This assessment focuses on the intended use and proposed indications for use of the product in question. In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class to which it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk. The three classes and the requirements which apply to them are:
   - Class I General Controls - With Exemptions/Without Exemptions
   - Class II General Controls and Special Controls - With Exemptions/Without Exemptions
   - Class III General Controls and Premarket Approval

   The class to which a device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market. General controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III. If a device is classified as Class I or II, and if it is not exempt, a 510k will be required for marketing. All devices classified as exempt are subject to the limitations on exemptions. Limitations of device exemptions are covered under 21CFR xxx.9, where xxx refers to Parts 862-892.
Information about exemptions can be found here: Medical Device Exemptions. To find the classification of a device, as well as whether any exemptions may exist, the regulation number needs to be found. Each classification panel in the Code of Federal Regulations (CFR) begins with a list of devices classified in that panel. Each classified device has a 7-digit number associated with it, ex. 21 CFR 880.920 – Clinical Mercury Thermometer. Most medical devices can be classified by finding the matching description of the device in title 21 of CFR parts 862-892. Classification product codes are used by CDRH to classify and monitor medical devices. Classification product codes and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation. The product code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.

There are two methods for finding the regulation number and classification: Go directly to the classification database and search for a part of the device name, OR, if the device panel (medical specialty) to which the device belongs is known, go directly to the listing for that panel and identify the device and the corresponding regulation.

3. Predicate Device

The legally marketed device(s) to which substantial equivalence is drawn is known as the predicate device(s). A claim of substantial equivalence does not mean the device(s) must be identical. Substantial equivalence is established with respect to: intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics. A device recently cleared under 510(k) is usually used as a predicate device.

However, any legally U.S. marketed device may be used as a predicate. This includes: a device that has been cleared through the 510(k) process; a device that was legally marketed prior to May 28, 1976 (pre-amendments device); a device that was originally on the U.S. market as a Class III device (Premarket Approval) and later down classified to Class II or I; or a 510(k) exempt device. The FDA 510(k) database contains all devices cleared under the 510(k) process. The FDA databases are updated on or around the 5th of every month. The classification of the device and product code is essential in searching for predicate devices. Once classification for the device is found, begin to search in the 510(k) Database.

Information which can be useful to find a predicate device includes:

- Names of similar devices - traded name under which the device is marketed
- Manufacturer(s) of the similar device(s)
- Marketing status, i.e., pre-amendments or post-amendments device
- 510(k) numbers for post-amendments devices
- Classification information, i.e., product codes, classifying regulations, etc., for the device

Several methods of searching the FDA database may be necessary. It is usually best to complete only one box in the online search form per search. The search engine searches for an exact match of text. Therefore, one descriptive word in the “device name” box is recommended. Only FDA generated product codes will work with the 510(k) and other FDA databases. 510(k)’s for similar device types are usually linked in the 510(k) database by the same product code. While this is not always true, it is the case with enough regularity that searching for predicate devices by product code is usually the most effective (leaving the other boxes blank).

Alternatively, if the manufacturer name(s) for a similar device is known, search the database by manufacturer name. Hyphens or spaces in names can make a difference, so try different combinations of the manufacturer’s name if the search results in “no records found.” Please note that the 510(k) database contains original application information only. That is, it maintains the name of the original applicant and the original trade name provided in the 510(k). It is not updated to reflect the current owner or distributor of the product nor any changes in trade name.

4. Performance Tests Required

There are seven general safety and performance requirements that apply to all medical devices products. There are a further eleven design and manufacturing requirements, some of which are relevant to each medical device. The design and manufacturing requirements are grouped as:
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The product innovator selects which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding any others. Typically, the specific testing requirements are determined while establishing the Product Requirements. The performance testing requirements are based on several factors, including: 1) user/market needs, 2) potential failure modes and functions specific to the device, and 3) industry standards and guidance documents.

5. Data Requirements

- **Pre-clinical**

  The first step is to consider bench, animal, biocompatibility, software, electromagnetic compatibility or other studies that may be necessary to support the investigational and/or marketing applications for the device. A review of studies done to date may reveal existing data that could be leveraged. For areas in which no evidence exists, new studies will be required. Be sure to determine whether new test methodologies must be developed due to novel aspects of the device. Document the voluntary or mandatory standards the product will be designed to meet and how conformance to those standards will be demonstrated.

  Standards are drawn up at international, regional and national level. There are 3 major international standardization bodies:

  - International Electro-technical Commission (IEC) for electricity, electronics and related technologies;
  - International Telecommunications Union (ITU) for telecommunications and radio communications;
  - International Organization for Standardization (ISO) for nearly all other technical fields, service sectors, management systems and conformity assessment.

  Examples of standards bodies at the national levels are Association for the Advancement of Medical Instrumentation (AAMI), American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI), etc.

6. Clinical

Describe the clinical evidence that must be obtained to support safety and effectiveness, and identify the studies that would need to be conducted. Consider main design elements that would be required, including the sampling frame, number of subjects, clinical setting, methods, outcomes and duration of study. These will be informed by the intended uses. Provide an overview of the intended timeline for the clinical investigations.

7. Options for Engaging FDA

- **513(g) Request for Information**

  In cases where there is no clearly appropriate classification regulation and/or suitable predicate, the company can seek greater certainty regarding the product’s regulatory status via the formal Section 513(g) Request for Information process. To obtain a 513(g) determination from FDA, the manufacturer must submit a description of the product, the proposed intended use and indications for use, and its proposed classification to the agency for review. FDA responds with a letter within 60 days addressing whether the product is considered a medical device, and if so, stating its classification and whether it will be subject to active regulation or enforcement discretion. Importantly, while FDA’s response to a 513(g) request does not constitute clearance or approval...
and is non-binding on the agency, a decision that the product requires premarket clearance or approval would likely be considered binding on the submitter.

It is typically not recommended to file a 513(g) where it appears that a medical device will require a marketing submission (i.e., 510(k) notice, de novo petition, or PMA), but rather only where a company is seeking to confirm that a product is either: (1) 510(k)-exempt; or (2) is a consumer or wellness product, and not a medical device.

○ Informal Inquiries to CDRH

Informal inquiries to the appropriate branch within CDRH can also be made in addition to other avenues to obtain an informal read on the agency’s likely position on device classification. Such communications are highly informal and in no way binding on the agency; any feedback is only the opinion of one person, and an entire review team may well not agree with that individual opinion. Still, such informal feedback could help in deciding whether to proceed with another option, such as a 513(g) request.

○ Pre-submission Feedback

In situations where a product is a medical device that will almost certainly require a marketing submission, and the data supporting that marketing submission and/or the regulatory pathway are uncertain, then the pre-submission process can be utilized to obtain agency feedback prior to filing of a marketing submission. The pre-submission process facilitates a dialogue with FDA whereby the sponsor proposes both the data that would support a marketing submission and the regulatory pathway for the product, and the agency reacts to that proposal. The initial step in this process is the submission of a package of information to FDA that includes information on the device, a proposed indications for use statement, details of the testing conducted to date, a detailed proposal (and ideally full protocol) for planned preclinical and clinical studies, a summary of the proposed regulatory pathway, questions for which the company is seeking feedback, and other required administrative information.

Following the filing of the pre-submission package, FDA grants a meeting or teleconference, generally within 6 to 8 weeks, although the agency technically has up to 90 days to meet with a sponsor. In situations where both clinical evidence and questions on the regulatory pathway are at issue, an in-person meeting is recommended as this provides the best possibility of a favorable outcome.

8. Regulatory Pathway - Determine Regulatory Options

The following information is taken directly from “Developing an Effective Regulatory Strategy” by Mark D. Kramer, MS, RAC.

Describe how the device will be regulated, the relevant agency guidance and key data considerations based upon the regulatory information gathered above. Describe any publicly available information about the regulatory strategies used for, and apparent successes and/or pitfalls of, competitive products. Identify the key risks or barriers and any critical assumptions, issues or questions that must be confirmed or resolved, and anticipate how prior or current requirements might evolve over the product development timeline. Some specific recommendations for key pathway issues to define and document:

○ If there are several options for the regulatory pathway, identify them, along with the advantages and disadvantages of each for the company. Though it may often turn out to be the best choice, resist the temptation to automatically select the fastest route to market. For example, in the US, positioning the product as a PMA device might provide greater long-term gains in market exclusivity, claims or reimbursement despite the historically longer approval time compared to a 510(k).

○ If the device is determined to follow the 510(k) pathway, provide a detailed comparison of the proposed predicate devices with respect to all key characteristics that are significant from a regulatory perspective. Identify any differences that may have regulatory significance and how these will be resolved. Be wary of reliance on so called “split predicates”.

○ Describe specific approaches planned for regulatory submissions, such as filing a Request for Designation for a combination product, requests for expedited review, paper vs. electronic submission, etc.
Implementing a regulatory strategy involves identifying projected timelines for key regulatory milestones such as agency meetings and submissions, and the resources, such as new hires, contractors or consultants, which will be required to meet those milestones. It is almost always prudent to confirm that the proposed regulatory strategy is sound (likely to be effective), practical (reasonable and efficient) and addresses company objectives. Circulate the draft strategy for review by the cross-functional team that was initially assembled. Despite care taken up front to fully understand the program, it is possible a key point was missed, or perhaps more likely, a change has emerged since initial meetings. Seek the feedback of others in the company, trusted colleagues or advisors to further vet the strategy. Set a schedule to periodically review and update the strategy document with the team. Keep a keen eye out for new information that may influence the regulatory strategy, which may include:

- Internally driven changes, such as company plans for new or revised indications or claims, device modifications or new markets
- Externally driven changes, such as new regulatory requirements or guidance or agency action on similar products

Implementation of Regulatory Strategy

A regulatory plan is a document that describes the specific steps and action required to successfully meet the regulatory strategy objectives. It contains the specific elements required to assemble the regulatory submission. Some key components might include: specific country regulatory references, a list of guidance and standards to be used, predicate devices and comparisons, a matrix of claims and the supporting data, labeling, specific pre-clinical and clinical reports, literature references and information or commitments from pre-submission meetings with regulatory agencies. The regulatory plan will establish specific project deliverables, timing, responsibilities and resource requirements. These should all be captured in sufficient detail to give the project team direction. The plan may be developed for each individual country submission or in a format that includes all planned country submission requirements.

Summary

- A solid regulatory strategy is one of the foundations upon which successful medical product development is based. Start by asking a broad range of questions to ensure there is a solid understanding of the product and marketing plans, especially any subtleties that may have regulatory impact.
- Conduct a regulatory landscape investigation to obtain as much information as possible about the regulation of similar or related products.
- Validate the strategy with internal and external stakeholders, and where appropriate, with agency personnel.
  - File a 513(g) if product code is unclear.
  - File a Pre-Submission to get feedback on the chosen pathway and on Intended use, Indications for use, safety tests, and advice on clinical or non-clinical evaluations/protocols. Results are not binding unless specific regulations are identified and added.
- Work with FDA, and explore every regulatory option - communication with FDA is most important. When seeking FDA approval of revolutionary technologies communicate early and communicate often. But there’s a caveat: Lead, don’t follow; Tell, don’t ask. It’s not their job to instruct, and a Pandora’s Box is opened if the innovator asks open ended questions. It’s the innovators job to figure out what to do: Come up with a plan that makes sense from an engineering perspective and from a biology perspective, and then go to FDA to sell it.
- Finally, closely watch product development and the regulatory environment, and be ready to revise the strategy as necessary.
USEFUL LINKS

Basic information and advice for device companies is available at the following websites:

- **Device Advice: Device Regulation and Guidance**
  - This website provides comprehensive technical and regulatory information about FDA requirements for medical devices.

- **Division of Industry Education (DICE) Homepage**
  - DICE answers questions from the medical device industry and develops educational resources to help the medical device industry understand FDA regulations and policies.

- **FDA Basics - Medical Devices**
  - Explains what medical devices are and how FDA regulates them.

- **Frequently Asked Questions (FAQs)**
  - Addresses medical device basics; the device review process; information about devices; and device safety.

- **Frequently Asked Questions about Medical Devices**
  - Information about IRBs, IDEs, Humanitarian Devices, Off-label use and unapproved devices plus more on basic FDA submissions.

- **CDRH Learn**
  - Consists of training modules that describe premarket and post-market aspects of medical device and radiological health regulation.

- **Device Classification**
  - A description of device classification

- **Product Classification Database**

- **Establishment registration and medical device listing**
  - Information about the basic regulatory requirements for medical device manufacturers

- **Premarket Notification 510(k)**

- **Premarket Approval (PMA)**

- **Investigational Device Exemption (IDE) for clinical studies**

- **Quality System (QS) regulation**

- **Labeling requirements**

- **Medical Device Reporting (MDR)**

- **Medical Device Regulations Global overview and guiding principles**