

## MEDICAL DEVICE REGULATIONS IN THE U.S. – THE BASICS

This paper is a general summary of food and medical device regulations administered by the U.S. Food and Drug Administration (FDA). There may be other laws or regulations, such as state laws, that affect food and/or medical device products.

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The United States (U.S.) regulates medical devices using a classification system based on the risk to the patient from using the device. Medical devices are classified into Class I (least risk), II, and III (most risk). Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from any clearance or preapproval requirement before they can be sold in the U.S. In other words, Class I devices can generally be sold without preapproval. Most Class II devices must receive prior clearance from the FDA before they can be sold in the U.S. The clearance process is known as “premarket notification” (the manufacturer notifies the FDA of its intention to market the device) and the application is referred to as a “510(k) application” based on the section of the U.S. Food, Drug and Cosmetic Act (FDCA) which authorizes the process. Most Class III devices must undergo a more exacting and expensive process, typically requiring clinical trials, known as “premarket approval” (PMA) before they can be sold in the U.S.

The following sections discuss the various types of regulations that apply to medical devices in the U.S.

### Establishment Registration and Device Listing - 21 CFR Part 807

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution (including importers) of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration. All establishment registrations must be submitted electronically unless a waiver has been granted by FDA. All registration information must be verified annually between October 1 and December 31 of each year. In addition to registration, foreign manufacturers must also designate a U.S. agent.

Further, most establishments are required to pay an establishment registration fee. There are no reductions in annual establishment registration fees for small businesses or any other group. The annual registration user fee for fiscal year 2016 is \$3,845 and is estimated to be \$3,872 for fiscal year 2017. The actual fee for fiscal year 2017 will be determined and posted by August 2016.



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Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. Establishments required to list their devices include:

- manufacturers
- contract manufacturers that commercially distribute the device
- contract sterilizers that commercially distribute the device
- repackagers and relabelers
- specification developers
- reprocessors of single-use devices
- remanufacturer
- manufacturers of accessories and components sold directly to the end user
- U.S. manufacturers of “export only” devices

If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also provide to the FDA premarket submission number (510(k), PMA, etc.).

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Among other things, this helps FDA plan facility inspection and increases the ability to prepare for and respond to public health emergencies.

## Premarket Notification 510(k) - 21 CFR Part 807 Subpart E

### A. Introduction

Each firm that wants to market a Class I, II, or III medical device in the U.S., for which a PMA is not required, must submit a 510(k) to FDA, unless the device is exempt from 510(k) requirements of the FDCA and does not exceed the limitations of exemptions noted in chapters that end in .9 of the device classification regulations (e.g., 21 CFR 862.9, 21 CFR 864.9). As noted above, many Class I devices are exempt and most Class III devices require a PMA, so the 510(k) process generally applies to Class II devices.

There is no 510(k) form; however, 21 CFR 807 Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from the FDA which finds the device to be substantially equivalent to a lawfully marketed devices and states that the device can be marketed in the U.S. This order “clears” (as distinct from approves) the device for commercial distribution.

A 510(k) application is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective as, or “substantially equivalent” to, a legally marketed device that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices, known as predicate devices, and make and support their substantial equivalency claims.

A legally marketed device, as described in 21 CFR 807.92(a)(3), is either (1) a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, (2) a device which has been reclassified by FDA from Class III to Class II or I, or (3) a device which has been found substantially equivalent through the 510(k) process. Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate.

Once the device is determined to be substantially equivalent, it can then be marketed in the U.S., but not before. The substantial equivalence determination is supposed to be made within ninety (90) days from FDA’s acceptance of the 510(k) submission, but 130 days is currently more typical. Further, a firm’s initial submission may require one or more revisions before FDA accepts it and starts a substantive review.

A firm may market the device immediately after 510(k) clearance is granted, without waiting for the FDA to inspect the facility where the device is made. The manufacturer should be prepared for an FDA quality system inspection (discussed below) at any time after 510(k) clearance.

## B. What is Substantial Equivalence?

As noted above, a 510(k) requires demonstration of substantial equivalence to another device that is lawfully marketed in the U.S. Substantial equivalence means that the new device is at least as safe and effective as the predicate. A device is substantially equivalent to a predicate device if, in comparison to the predicate, the device:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;

**or**

- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA;
- does not raise new questions of safety and effectiveness; **and**
- demonstrates that the device is at least as safe and effective as the legally marketed device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

If FDA determines that a device is **not** substantially equivalent, the applicant may:

- resubmit another 510(k) with new data
- request a Class I or II designation through the de novo process
- file a reclassification petition
- submit a premarket approval application (PMA).

## C. Who is Required to Submit a 510(k)?

The FDCA and the 510(k) regulation (21 CFR 807) do not specify who must apply for a 510(k). Instead, they specify which actions, such as introducing a device to the U.S. market, require a 510(k) submission. The following four categories of parties must submit a 510(k) to the FDA:

### 1. Domestic manufacturers introducing a device to the U.S. market.

Finished device manufacturers must submit a 510(k) if they manufacture a device according to their own specifications and market it in the U.S. Accessories to finished devices that are sold to the end user are also considered finished devices. Manufacturers of device components are not required to submit a 510(k), however, unless the components are promoted for sale to an end user as replacement parts. Contract manufacturers, those firms that manufacture devices under contract according to someone else's specifications, are not required to submit a 510(k).

### 2. Specification developers introducing a device to the U.S. market.

A specification developer develops the specifications for a finished device, but has the device manufactured under contract by another firm or entity. The specification developer submits the 510(k), not the contract manufacturer.

3. Repackers or relabelers who make labeling changes or whose operations significantly affect the device.

Repackagers or relabelers may be required to submit a 510(k) if they significantly change the labeling or otherwise affect any condition of the device. Significant labeling changes may include modification of manuals, such as adding a new intended use, deleting or adding warnings, contraindications, etc. Operations, such as sterilization, could alter the condition of the device. Most repackagers or relabelers, however, are not required to submit a 510(k).

4. Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

#### **D. When is a 510(k) is Required?**

A 510(k) is required when:

1. Marketing a device for the first time. A 510(k) is required if your device was not marketed by your firm before May 28, 1976 (the effective date of the Medical Device Amendments to the FDCA).
2. You propose a different intended use for a device that you already have in commercial distribution. Intended use is indicated by claims made for a device in labeling or advertising. The FDA's position is that most, if not all, changes in intended use will require a 510(k), including a change from prescription use to over the counter use.
3. There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness. The burden is on the 510(k) holder to decide whether or not a modification could significantly affect safety or effectiveness of the device.

#### **E. When a 510(k) is Not Required**

The following are examples of when a 510(k) is not required.

1. You sell unfinished devices to another firm for further processing or sell components to be used in the assembling of devices by other firms. A 510(k) is required, however, if your components are to be sold directly to end users as replacement parts.
2. Your device is not being marketed or commercially distributed. You do not need a 510(k) to develop, evaluate, or test a device. This includes clinical evaluation. Please note that if you perform clinical trials with your device, you are subject to the Investigational Device Exemption (IDE) regulation (discussed below).
3. You distribute another firm's device and it is made in the U.S. Assuming the manufacturer has obtained a 510(k), you may place a label on the device, "Distributed by ABC Firm" or "Manufactured for ABC Firm," and sell it to end users without submission of your own 510(k).
4. In most cases, if you are a repackager or a relabeler, you are not required to submit a 510(k) if the existing labeling or condition of the device is not significantly changed. The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use and warnings and contraindications.
5. Your device was lawfully marketed in the U.S. before May 28, 1976, and you have documentation to prove this. These devices are "grandfathered." You do not have to submit a 510(k) unless the device has been significantly modified or there has been a change in its intended use.
6. The device is made outside the U.S. and you are an importer of the foreign-made medical device. A 510(k) is not required if the foreign manufacturer submitted a 510(k) and received marketing clearance.

7. Your device is exempted from 510(k) by regulation (21 CFR 862-892). That is, certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A 510(k) is required, however, if the device exceeds the limitations of exemptions noted in chapters that end in .9 of the device classification regulations (e.g., 21 CFR 862.9, 21 CFR 864.9), such as the device has a new intended use or operates using a different fundamental scientific technology than a legally marketed device in that generic type of device, or the device is a reprocessed single-use device.

## **F. Fees**

The FDA charges a fee for medical device product reviews, including 510(k)s, PMAs, Product Development Protocols (PDPs), Biologics Licensing Applications (known as BLAs, these are certain medical devices reviewed by FDA's Center for Biologics Evaluation and Research), and certain supplements to those types of applications. The fee must be paid for these types of applications, unless the applicant is eligible for a waiver or exemption. Small businesses may qualify for a reduced fee. Payment must be received on or before the time the application is submitted. If the applicant has not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing.

## **Premarket Approval (PMA) - 21 CFR Part 814**

### **A. Introduction**

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 considered high-risk, i.e., those that support or sustain human life, are of substantial importance in preventing impairment of human health, which present a potential, unreasonable risk of illness or injury, or which are found not substantially equivalent through the 510(k) process. Because of the high level of risk associated with Class III devices, FDA has determined that general and special controls (such as registration, listing, and quality system regulation) alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a PMA application under section 515 of the FDCA to obtain marketing approval.

PMA is the most stringent type of device marketing application required by FDA. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer and, again, does not start until the FDA accepts the premarket approval application for filing. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission. After FDA notifies the applicant that the PMA has been approved or denied, a notice is published on the Internet (1) announcing the data on which the decision is based, and (2) providing interested persons an opportunity to petition FDA within 30 days for reconsideration of the decision.

### **B. When a PMA is Required**

PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices. Device product classifications can be found by searching the FDA's Product Classification Database. The database search provides the name of the device, classification, and a link to the Code of Federal Regulations (CFR), if any. The CFR provides the device type name, identification of the device, and classification information.

Please note that PMA devices often involve new concepts and many are not of a type marketed prior to the Medical Device Amendments. Therefore, they do not have a classification regulation in the CFR. In this case, the product classification database will only cite the device type name and product code.

If it is unclear whether the unclassified device requires a PMA, use the three-letter product code to search the PMA database and the Premarket Notification 510(k) database. These databases can be found by clicking on the hypertext links at the top of the product classification database web page. Enter only the three-letter product code in the product code box. If there are 510(k)s cleared by FDA and the new device is substantially equivalent to any of these cleared devices, then the applicant should submit a 510(k).

Furthermore, a new type of device may not be found in the product classification database. If the device is a high-risk device (supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury) and/or has been found to be not substantially equivalent (NSE) to a Class I, II, or III [Class III requiring 510(k)] device, then the device must have an approved PMA before it can be marketed in the U.S. Some devices that are found to be not substantially equivalent to a cleared Class I, II, or III (not requiring PMA) device, may be eligible for clearance as a Class I or Class II device through another process known as de novo.

### C. Data Requirements

A PMA application is a scientific, regulatory document submitted to FDA to demonstrate the safety and effectiveness of the Class III device. There are administrative elements of a PMA application, but good science and scientific writing is a key to the approval of a PMA application. If a PMA application lacks elements listed in the administrative checklist, FDA will refuse to file a PMA application and will not proceed with the in-depth review of scientific and clinical data. Applicants should perform a quality control audit of a PMA application before sending it to FDA to assure that it is scientifically sound and presented in a well-organized format.

**Technical Sections:** The technical sections containing data and information should allow FDA to determine whether to approve or disapprove the application. These sections are usually divided into non-clinical laboratory studies and clinical investigations.

**Non-clinical Laboratory Studies' Section:** The non-clinical laboratory studies' section includes information, where applicable, on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests. Non-clinical studies for safety evaluation must be conducted in compliance with 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies).

**Clinical Investigations' Section:** The clinical investigations' section includes study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations. Any investigation conducted under an Investigational Device Exemption (IDE) must be identified as such.

### D. Fees

PMA applications also require payment of fees. Because of the volume of data FDA must review, these fees are substantial, i.e., in the \$250,000 range and are also adjusted annually.

## Investigational Device Exemption (IDE) - 21CFR Part 812

An investigational device exemption (IDE) allows an investigational device to be used in a clinical study to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA, although only a small percentage of 510(k)s require clinical data to support the application. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk need only be approved by an IRB before the study can begin.

In addition to IRB and/or FDA approval, clinical evaluation of devices that have not been cleared for marketing requires:

- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study, and
- required records and reports.

An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the FDCA that would apply to devices in commercial distribution. Sponsors need not submit a PMA or Premarket Notification 510(k), register their establishment, or list the device while the device is under investigation. Sponsors of IDEs are also exempt from the Quality System (QS) Regulation except for the requirements for design controls (21 CFR 820.30).

## Good Clinical Practices (GCP)

Good Clinical Practices (GCP) refers to the regulations and requirements that must be complied with while conducting a clinical study. These regulations apply to the manufacturers, sponsors, clinical investigators, IRBs, and the medical device. The primary regulations that govern the conduct of clinical studies are:

- 21 CFR 812, Investigational Device Exemptions: Covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, and reports.
- 21 CFR 50, Protection of Human Subjects: Provides the requirements and general elements of informed consent.
- 21 CFR 56, Institutional Review Boards: Covers the procedures and responsibilities for IRBs that approve clinical investigations protocols.
- 21 CFR 54, Financial Disclosure by Clinical Investigators: Covers the disclosure of financial compensation to clinical investigators which is part of FDA's assessment of the reliability of the clinical data
- 21 CFR 820 Subpart C, Design Controls of the Quality System Regulation: Provides the requirement for procedures to control the design of the device in order to ensure that the specified design requirements are met.

## Quality System Regulations (QSR)/Good Manufacturing Practices (GMP) - 21 CFR Part 820

The quality system regulations include requirements related to the methods used in and the facilities and controls used for designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. FDA inspects manufacturing facilities to ensure compliance with the QSR requirements.

### A. Introduction

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and devices) are known as current good manufacturing practices (CGMPs). CGMP requirements for devices are found at 21 CFR Part 820.

## **B. Flexibility of the QS Regulation**

Because the QS regulations must apply to many different types of devices, the regulation embraces an “umbrella” approach rather than prescribing in detail how a manufacturer must produce a specific device. The regulations provide the framework that all manufacturers must follow by requiring manufacturers to develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.

Manufacturers should use good judgment when developing their quality system and apply those sections of the QS regulation that are applicable to their specific products and operations. Operating within this flexibility, each manufacturer has the responsibility to establish requirements for each type or family of devices that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements. The responsibility for meeting these requirements and for having objective evidence of meeting these requirements may not be delegated, even though the actual work may be delegated.

FDA has identified in the QS regulation the essential elements that a quality system must embody, without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices, production processes, etc., it allows some leeway in the details of quality system elements. It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices.

## **C. Applicability of the QS Regulation**

The QS regulations apply to finished device manufacturers who intend to commercially distribute medical devices. A finished device is defined in 21 CFR 820.3(l) as any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Certain components such as blood tubing and diagnostic x-ray components are considered by FDA to be finished devices because they are accessories to finished devices. A manufacturer of accessories is subject to the QS regulation.

## **D. GMP Exemptions**

FDA has determined that certain types of medical devices are exempt from GMP requirements. These devices are exempted by FDA classification regulations published in the Federal Register and codified in 21 CFR 862 to 892. Exemption from the GMP requirements does not exempt manufacturers of finished devices from keeping complaint files (21 CFR 820.198) or from general requirements concerning records (21 CFR 820.180). As noted above, medical devices manufactured under an IDE are not exempt from design control requirements under 21 CFR 820.30 of the QS regulations.



## Labeling - 21 CFR Part 801

Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device. As explained below, the term “accompanies” has been construed broadly so that almost any information about a device disseminated by the manufacturer, including information on internet websites, may be found to “accompany” the device.

### A. Introduction to Medical Device Labeling

#### 1. Label vs. Labeling

Labeling regulations pertaining to medical devices are found in the following Parts of Title 21 of the CFR:

- General Device Labeling - 21 CFR Part 801
- In Vitro Diagnostic Products - 21 CFR Part 809
- Investigational Device Exemptions - 21 CFR Part 812
- Good Manufacturing Practices - 21 CFR Part 820
- General Electronic Products - 21 CFR Part 1010

Section 201(k) of the FDCA defines “label” as a:

- “display of written, printed, or graphic matter upon the immediate container of any article...”

The term ‘immediate container’ does not include package liners. Any word, statement, or other information appearing on the immediate container must also appear “on the outside container or wrapper, if any there be, of the retain package of such article, or is easily legible through the outside container of wrapper.”

Section 201(m) of the FDCA defines ‘labeling’ as:

- “all labels and other written, printed, or graphic matter
  - (1) upon any article or any of its containers or wrappers, or
  - (2) accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.”

As noted above, the term “accompanying” is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. “Accompanying” also includes labeling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

### B. Advertising

According to an appellate court decision: “Most, if not all advertising, is labeling. The term ‘labeling’ is defined in the FFDCAs as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.”

## Medical Device Reporting - 21 CFR Part 803

Incidents in which a device may have caused or contributed to a death or serious injury must be reported to FDA under the Medical Device Reporting program. In addition, certain malfunctions must also be reported. The MDR regulations are a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.

### A. Mandatory Medical Device Reporting

The MDR regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities (e.g., hospitals) to report certain device-related adverse events and product problems to the FDA. Reports must be filed on FDA Medwatch Form 3500A in electronic equivalent.

Information on the requirements for each mandatory reporting group follows:

**Manufacturers:** Manufacturers are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury. (Key terms are defined in 21 CFR 803.3.) Manufacturers must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

**Importers:** Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

### Summary of Mandatory Reporting Requirements for Manufacturers and Importers

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
<b>Manufacturers</b>	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	Form FDA 3500A	FDA	Within 5 work days of becoming aware of an event
<b>Importers</b>	Reports of deaths and serious injuries	Form FDA 3500A	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Form FDA 3500A	Manufacturer	Within 30 calendar days of becoming aware of an event

## **B. Device User Facility Reporting Requirements**

A “device user facility” is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician’s office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

User facilities must also submit annual reports to the FDA by January 1 of each year as described in 21 CFR 803.33.

## **C. Complaint Files and Medical Device Reporting**

Complaint files are linked to MDR event files because a complaint must be evaluated to determine if it is a reportable adverse event. A complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Manufacturers and importers are required to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints. Importers are also subject to complaint files because “initial distributors of foreign entities” fall under the definition of a manufacturer in 21 CFR 820.3.

Complaint files that are found to be reportable MDR events should be maintained in a separate portion of the complaint file or otherwise clearly identified.

## **Importing Medical Devices**

Foreign firms that manufacture medical devices and/or products that emit radiation that are imported into the U.S. must comply with applicable U.S. regulations before, during, and after importing into the U.S. or its territories. To import medical devices and/or products that emit radiation into the U.S., the product must meet and the manufacturer must comply with the FDA regulatory requirements summarized above. FDA does not recognize regulatory approvals from other countries. The following is a summary of FDA requirements for medical devices and products that emit radiation.

### **Import Process**

All medical devices that are imported into the U.S. must meet Bureau of Customs and Border Protection (CBP) requirements in addition to FDA requirements. A product that does not meet FDA regulatory requirements may be detained upon entry.

The major responsibility of CBP is to administer the Tariff Act of 1930 as amended. Primary duties include assessment and collection of all duties, taxes, and fees on imported merchandise; administration and review of import entry forms; the enforcement of CBP and related laws; and administration of certain navigation laws and treaties. There is a working agreement between FDA and CBP for the cooperative enforcement of Section 801 of the FDCA.

The import process begins with the importer or filer submitting the necessary entry information to the local CBP district office. For those entries not filed electronically, a paper entry consisting of the commercial invoice, CBP entry forms CF3461/3461ALT and/or CF7501 need to be provided by the importer or filer.

Entry information should identify the product and include appropriate information to demonstrate that the product is in compliance with FDA regulations. Product information should include device name and product code. The correct information will help expedite the entry review process and increase the likelihood that your shipment may be processed based on an import system screening and not held for further FDA entry review. Please note that the product code provided to CBP must include a two digit prefix identifying the medical specialty in addition to the three letter code. The medical specialty codes are as follows:

<b>NUMBER</b>	<b>MEDICAL SPECIALTY</b>	<b>REGULATIONS</b>
<b>73</b>	Anesthesiology	Part 868
<b>74</b>	Cardiovascular	Part 870
<b>75</b>	Chemistry	Part 862
<b>76</b>	Dental	Part 872
<b>77</b>	Ear, Nose, and Throat	Part 874
<b>78</b>	Gastroenterology and Urology	Part 876
<b>79</b>	General and Plastic Surgery	Part 878
<b>80</b>	General Hospital	Part 880
<b>81</b>	Hematology	Part 864
<b>82</b>	Immunology	Part 866
<b>83</b>	Microbiology	Part 866

NUMBER	MEDICAL SPECIALTY	REGULATIONS
84	Neurology	Part 882
85	Obstetrics and Gynecology	Part 884
86	Ophthalmics	Part 886
87	Orthopedics	Part 888
88	Pathology	Part 864
89	Physical Medicine	Part 890
90	Radiology	Part 892
91	Toxicology	Part 862

For example, the device product code provided to CBP for sunglasses would be 86HQY.

Most importers ask that domestic customhouse brokers (or filers) complete these forms electronically and make the submissions on their behalf. Filers have access to the Operational and Administrative Systems for Import Support (OASIS), the FDA computerized import system. The OASIS program is an electronic interface between FDA and the CBPs Automated Commercial System (ACS). OASIS is an on-line interactive and automated system, which replaced the process of reviewing the paperwork for import entries manually.

When an entry is filed with CBP, a copy of the entry is also provided to the local FDA district office. The FDA district office then determines if the product complies with FDA requirements. The FDCA authorizes FDA to detain a regulated product that appears to be out of compliance with the Act. If a product appears to be out of compliance, the FDA district office will issue a “Notice of FDA Action” specifying the nature of the violation to the owner or consignee. The owner or consignee is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another “Notice of FDA Action” refusing admission to the product. The product then has to be exported or destroyed within 90 days. Failure to do so within 90-days may result in issuance of a Customs Redelivery Notice and an assessment for liquidated damages for up to three (3) times the value of the lot.

Upon entry, FDA may examine certain devices to assure their safety and effectiveness. When this occurs, FDA will issue a notice to the importer of record on a “Notice of FDA Action” form. Sampling may involve examining the product at the port of entry or physical collection of a statistical portion of the lot for analysis by an FDA laboratory. If the sample is violative, or if the sample is determined to be out of compliance with required specifications, the device will be detained and the importer of record will be issued another “Notice of FDA Action” indicating that the article is being detained due to the appearance of a violation of the FDCA. The “Notice of FDA Action” will state the specific violations of the FDCA.

Under certain conditions, the importer of record of a device that has been detained may be given an opportunity to submit application for authorization to bring the device into compliance with the FDCA. If FDA permits reconditioning, another sample may be collected and analyzed after reconditioning. If the device is then determined to be in compliance, it will be released. Only the FDA District Office at the port of entry has the authority to authorize reconditioning and/or to release the shipment. You must provide the appropriate documentation or bring the products into compliance with the authorization of the District Office. When contacting the District Office, you should ask for the Compliance Office and provide the entry number and/or sample number as a reference.