

Peter Quinter, Shareholder

Best Practices For Importing Medical Devices

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What is a Medical Device?

- The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
 - (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

What is a Medical Device?

- Examples of Medical Devices:
 - Pacemakers
 - Contact Lenses
 - Hearing Aids
 - Dental Floss
 - Thermometer

Federal Food, Drug and Cosmetic Act

- Imported medical devices must fully comply with the Federal Food, Drug and Cosmetic Act (as amended) before the device is released by Customs.
- For further information, see FDA's Office of Regulatory Affairs Import Start Page accessible at: (www.fda.gov/ora/import/default.htm)

FDA`s Center for Devices and Radiological Health

- FDA`s Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repack, relabel, and/or import medical devices sold in the United States.

CHECKLIST

TO IMPORT MEDICAL DEVICES

- Premarket Notification (510(k)), unless exempt, or Premarket Approval (PMA)
- Establishment Registration on Form FDA-2891
- Device Listing on Form FDA-2892
- Quality System Regulation (QSR) (sometimes referred to as good manufacturing practices or GMPs)
- Labeling Requirements
- Medical Device Reporting
- U.S. Designated Agent (for imported devices)
(<http://www.fda.gov/cdrh/usagent>)

Medical Devices Classes

- The Food and Drug Administration (FDA) established classifications for approximately 1,700 different generic types of devices.
- Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device.

Medical Devices Classes

- Device classification depends on the *intended use* of the device and also upon *indications for use*.
- For example, a scalpel's intended use is to cut tissue.

Medical Devices Classes

- The class to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market.

Medical Devices Classes

- Use the Classification Database to determine what Class your device is:
 - (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm)

The screenshot shows the FDA's Classification Database search page. At the top, it features the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below this is the "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" header. A navigation bar contains links for "FDA Home Page", "CDRH Home Page", "Search", "CDRH A-Z Index", and "Contact CDRH". A secondary navigation bar lists various regulatory topics: "510(k)", "Registration", "Listing", "Adverse Events", "PMA", "Classification", "CLIA", "CFR Title 21", "Advisory Committees", "Assembler", "Recalls", "Guidance", and "Standards". The main section is titled "Search Classification Database" and includes links for "Help", "Download Files", and "More About Classification". The search form contains several input fields and dropdown menus: "Device" (text input), "Product Code" (text input), "Review Panel" (dropdown menu), "SubmissionType" (dropdown menu), "Regulation Number" (text input), "Third Party Eligible" (dropdown menu), "Sort By" (dropdown menu with "Device Name (A-Z)" selected), and "Device Class" (dropdown menu). At the bottom of the form, there is a note: "For full-text search, select Go To Simple Search button". The footer of the form includes a "Search" button, a "Clear" button, a "50" dropdown menu, the text "Records per Report Page", and a "Go to Simple Search" button.

Medical Devices Classes

- **CLASS I** – most are exempt from Premarket Notification (510(k))
- **CLASS II** – most require a Premarket Notification (510(k))
 - Most Class I devices and some Class II devices are exempt from 510(k) submission. A list of exempt devices is located at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>
- **CLASS III** – those that support or sustain human life, most require a Premarket Approval (PMA)

Premarket Notification – 510 (k)

- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device
- Normally Class II devices

Who must submit a 510 (k)?

- Domestic manufacturers introducing a device to the U.S. market;
- Specification developers introducing a device to the U.S. market;
- Repackers or relabelers who make labeling changes or whose operations significantly affect the device.
- Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market

Premarket Notification – 510 (k)

- Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims.
- A legally marketed device, is a device that was legally marketed prior to May 28, 1976 for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process.

Premarket Notification – 510 (k)

- Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device.
- Once the device is determined to be SE, it can then be marketed in the U.S.
- The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.

510 (k) – Substantial Equivalence

- A device is substantially equivalent if, in comparison to a predicate it:
 - has the same intended use; **and**
 - has the same technological characteristics; OR
 - has the same intended use; **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.

510 (k) – Substantial Equivalence

- 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
 - (An applicant of a 510(k) who receives a Not Substantially Equivalent (NSE) determination placing the device into a Class III category can request a de novo classification of the product into Class I or II)
 - 60 day review period
 - file a reclassification petition, or
 - 180 day review period
 - submit a premarket approval application (PMA).

Premarket Approval (PMA)

- Product requiring PMAs are **Class III** devices are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process.
- The PMA process is more involved and includes the submission of clinical data to support claims made for the device.

Premarket Approval (PMA)

- The PMA is an actual approval of the device by FDA.
- FDA has 180 days to review the PMA and make a determination (usually takes longer)
- A description of the process and instructions for filing a PMA application can be found at: <http://www.fda.gov/cdrh/devadvice/pma/>.

Premarket Approval (PMA)

- Beginning fiscal year 2003 (October 1, 2002 through September 30, 2003), medical device user fees apply to original PMAs and certain types of PMA supplements.
- Small businesses are eligible for reduced or waived fees.
- Additional information on medical device user fees, including how to qualify as a small business, is available at <http://www.fda.gov/cdrh/devadvice/pma/userfees.html>.

Establishment Registration – FDA Form 2891

- Once Form 2891 is filed with the FDA, the manufacturer will receive a:
 - Owner/Operator Number (within 5 business days)
 - Registration Number (within 30-90 business days)

Establishment Registration – FDA Form 2891

- Check to see if a Manufacturer has registered its establishment (by name, Registration Number, Owner/Operator Number):
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/registration.cfm>

The screenshot shows the FDA Center for Devices and Radiological Health website. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration" and "Department of Health and Human Services". Below this, there is a search bar and a "Search" button. The main content area features a "Search Registration Database" section with the following fields:

- Establishment Name:
- Establishment Registration Number:
- Owner/Operator Number:
- Sort by:

Below the search fields, there is a note: "For full-text search, select Go To Simple Search button". At the bottom of the search section, there are buttons for "Go to Simple Search", "10 Records per Report Page", "Search", and "Clear".

Establishment Registration – FDA Form 2891

- The Initial Importer must list its establishment as well (they must file a separate Form 2891 from the manufacturers).

Establishment Registration

– FDA Form 2891

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		1. REGISTRATION NUMBER	FORM APPROVED: OMB No. 0910-0387 EXPIRATION DATE: April 30, 2008																																			
REGISTRATION OF DEVICE ESTABLISHMENT		2. OWNER/OPERATOR NUMBER	VALIDATION (FDA USE ONLY)																																			
<p>Submit an original copy. Please do not mail the instruction pages with your form (this page only). Return form to: Food and Drug Administration, Center for Devices & Radiological Health, HFZ- 308, 9200 Corporate Blvd, Rockville, MD 20850-4015</p>		<p>6. REASON FOR UPDATE (check all that apply)</p> <p><input type="checkbox"/> 6.1 Establishment Name Change</p> <p><input type="checkbox"/> 6.2 Establishment Type Change (deletion or addition)</p> <p><input type="checkbox"/> 6.3 Establishment Address Change - Merged with Other Establishment</p> <p><input type="checkbox"/> 6.4 Establishment Address Change - Moved to New Location</p> <p><input type="checkbox"/> 6.5 Official Correspondent Name/Address Change</p> <p><input type="checkbox"/> 6.6 U.S. Agent Change</p> <p><input type="checkbox"/> 6.7 Owner/Operator Name/Address Change - Same Company New Name or Address</p> <p><input type="checkbox"/> 6.8 Owner/Operator Change - Sold Establishment</p> <p><input type="checkbox"/> 6.9 Out of Business</p> <p><input type="checkbox"/> 6.10 No Longer a Device Establishment</p> <p><input type="checkbox"/> 6.11 In Production</p> <p><input type="checkbox"/> 6.12 Trade Name or Establishment URL Change</p>		<p>Establishment Types (check all that apply)</p> <table border="1"> <thead> <tr> <th>Add</th> <th>Delete</th> <th></th> </tr> </thead> <tbody> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.1 Contract Manufacturer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.2 Contract Sterilizer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.3 Foreign Exporter</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.4 Initial Distributor/Importer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.5 Manufacturer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.6 Remanufacturer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.7 Repackager/Relabeler</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.8 Reprocessor of Single Use Devices</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.9 Specification Developer</td></tr> <tr><td><input type="checkbox"/></td><td><input type="checkbox"/></td><td>7.10 U.S. Manufacturer of Export Only Devices</td></tr> </tbody> </table>		Add	Delete		<input type="checkbox"/>	<input type="checkbox"/>	7.1 Contract Manufacturer	<input type="checkbox"/>	<input type="checkbox"/>	7.2 Contract Sterilizer	<input type="checkbox"/>	<input type="checkbox"/>	7.3 Foreign Exporter	<input type="checkbox"/>	<input type="checkbox"/>	7.4 Initial Distributor/Importer	<input type="checkbox"/>	<input type="checkbox"/>	7.5 Manufacturer	<input type="checkbox"/>	<input type="checkbox"/>	7.6 Remanufacturer	<input type="checkbox"/>	<input type="checkbox"/>	7.7 Repackager/Relabeler	<input type="checkbox"/>	<input type="checkbox"/>	7.8 Reprocessor of Single Use Devices	<input type="checkbox"/>	<input type="checkbox"/>	7.9 Specification Developer	<input type="checkbox"/>	<input type="checkbox"/>	7.10 U.S. Manufacturer of Export Only Devices
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<p>3. TODAY'S DATE (mm/dd/yyyy)</p>		<p>7. U.S. AGENT NAME AND ADDRESS (Foreign Establishments Only)</p> <p>Same as Official Correspondent? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>(If No, List Individual's Name, Title, Business Name, Number & Street, City, State, ZIP code.) No P.O. Boxes. The U.S. Agent must either reside in the U.S. or maintain a place of business there.</p>																																				
<p>4. TYPE OF REGISTRATION</p> <p><input type="checkbox"/> 4.1 Initial <input type="checkbox"/> 4.2 Update <input type="checkbox"/> 4.3 Preproduction</p>		<p>8. ESTABLISHMENT (No P.O. Boxes)</p> <p>Business Name</p> <p>Number & Street</p> <p>City State ZIP Code</p> <p>Foreign State Postal Code Country</p>																																				
<p>5. REQUIRED TO SUBMIT DEVICE LISTING (Form FDA 2892)?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No; If No, Explain:</p>		<p>9. OFFICIAL CORRESPONDENT (Name of individual is required)</p> <p>Reason for OC Name Change (see instructions):</p> <p>Name</p> <p>Title</p> <p>Business Name</p> <p>Number & Street</p> <p>City State ZIP Code</p> <p>Foreign State Postal Code Country</p>																																				
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<p>11. OWNER/OPERATOR (No P.O. Boxes)</p> <p>Business Name</p> <p>Number & Street</p> <p>City State ZIP Code</p> <p>Foreign State Postal Code Country</p>		<p>11.1 PHONE NO. (Phone no. should include area code or country/city codes)</p> <p>9.1 EMAIL</p> <p>10.1 EMAIL</p> <p>9.2 PHONE NO. (Phone no. should include area code or country/city codes)</p> <p>10.2 PHONE NO. IN U.S. (Phone no. should include area code)</p> <p>9.3 FAX NO. (FAX no. should include area code or country/city codes)</p> <p>10.3 FAX NO. IN U.S. (FAX no. should include area code)</p>																																				
<p>12. OTHER BUSINESS TRADING NAMES</p>		<p>13.1 PRINTED NAME (Mr., Miss., Mrs., Ms., Dr.)</p> <p>13.2 TITLE</p>																																				
<p>13. SIGNATURE OF OFFICIAL CORRESPONDENT</p>		<p>14. ESTABLISHMENT'S URL (Optional):</p>																																				
<p>NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.</p>		<p>FOR OFFICIAL USE ONLY</p> <p>O / W / P / Y</p>																																				

Medical Device Listing - FDA Form 2892

- Most medical device establishments required to register with FDA must also identify to FDA the devices they have in commercial distribution including devices produced exclusively for export.
- This process is known as medical device listing and is a means of keeping FDA advised of the generic category(s) of devices an establishment is manufacturing or marketing.

Medical Device Listing - FDA Form 2892

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DEVICE LISTING		Complete and Return Only the Original Form to: Please do not mail the instruction pages with your form. Food and Drug Administration Center for Devices & Radiological Health, HFZ-308 9200 Corporate Blvd., Rockville, MD 20850-4015	Form Approved: OMB No. 0910-0387 Expiration Date: April 30, 2008	1. TODAY'S DATE (mm/dd/yyyy)	
NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 351(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.					
2. OWNER/OPERATOR NUMBER		4. REGISTRATION NUMBER			
3. OWNER/OPERATOR NAME (Business name)		5. ESTABLISHMENT NAME (Business name)			
NUMBER AND STREET		NUMBER AND STREET			
CITY	STATE	ZIP CODE	CITY	STATE	ZIP CODE
FOREIGN STATE	POSTAL CODE	COUNTRY	FOREIGN STATE	POSTAL CODE	COUNTRY
6. LISTING INFORMATION: Number of product codes you are going to list for this establishment:					
REASON FOR LISTING: <input type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing			REASON FOR LISTING: <input type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing		
PRODUCT CODE	PMA NUMBER	510(k) NUMBER	PRODUCT CODE	PMA NUMBER	510(k) NUMBER
CLASSIFICATION NAME			CLASSIFICATION NAME		
PROPRIETARY NAME			PROPRIETARY NAME		
COMMON OR USUAL NAME			COMMON OR USUAL NAME		
PREVIOUS LISTING NUMBER	LISTING NUMBER	PREVIOUS LISTING NUMBER	LISTING NUMBER	PREVIOUS LISTING NUMBER	LISTING NUMBER
<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Foreign Exporter	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Remanufacturer <input type="checkbox"/> Repackager/Relabeler	<input type="checkbox"/> Reprocessor of Single Use Devices <input type="checkbox"/> Specification Developer <input type="checkbox"/> U.S. Manufacturer of Export Only Devices	<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Foreign Exporter	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Remanufacturer <input type="checkbox"/> Repackager/Relabeler	<input type="checkbox"/> Reprocessor of Single-use device <input type="checkbox"/> Specification Developer <input type="checkbox"/> U.S. Manufacturer of Export Only Devices
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PRODUCT CODE	PMA NUMBER	510(k) NUMBER	PRODUCT CODE	PMA NUMBER	510(k) NUMBER
CLASSIFICATION NAME			CLASSIFICATION NAME		
PROPRIETARY NAME			PROPRIETARY NAME		
COMMON OR USUAL NAME			COMMON OR USUAL NAME		
PREVIOUS LISTING NUMBER	LISTING NUMBER	PREVIOUS LISTING NUMBER	LISTING NUMBER	PREVIOUS LISTING NUMBER	LISTING NUMBER
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7. SIGNATURE OF OFFICIAL CORRESPONDENT		8. TYPED OR PRINTED NAME		TITLE	
FORM FDA 2892 (6/05) (PREVIOUS FORMS ARE OBSOLETE) Note: Validation of this form is not to be construed as FDA approval of the establishment or its products.					

Quality System Regulation (QSR)

- Also referred to as Good Manufacturing Practices (GMP)
- The quality system regulation includes 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.
- Perform your Due Diligence!

Quality System Regulation (QSR)

- The quality system regulation includes design controls which must be complied with during the design and development of the device. Information on design controls can be found in the following guidance documents:
 - Design Control Guidance for Medical Device Manufacturers
<http://www.fda.gov/cdrh/comp/designqd.html>
 - The guidance document, "Medical Device Quality Systems Manual: A Small Entity Compliance Guide" is available on the Internet at:
<http://www.fda.gov/cdrh/dsma/gmpman.html>

Quality System Regulation (QSR) - Labeling

- Labeling includes labels on the device as well as descriptive and informational literature that accompanies the device.
- Labeling requirements can be accessed on the web at:
<http://www.fda.gov/cdrh/devadvice/33.html>

OVERVIEW OF DUE DILIGENCE REQUIREMENTS

DUE DILIGENCE

- **What is the premarket review/approval requirement for the device, and has it been met?**
 - Premarket Notification (510(k)) Exempt
 - Premarket Notification (510(k)) – obtain copy of letter showing the device has been deemed “substantially equivalent”
 - Premarket Approval (PMA)

DUE DILIGENCE

- Does the foreign manufacturer, and initial importer or distributor have a current Establishment Registration?
- Check FDA Website: Check FDA Website:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/registration.cfm>

The screenshot displays the FDA website's search interface for the Establishment Registration Database. At the top, the FDA logo is present with a tooltip indicating it links to the home page. The header includes the text 'U.S. Food and Drug Administration' and 'Department of Health and Human Services'. Below this, the 'CENTER FOR DEVICES AND RADIOLOGICAL HEALTH' is identified, along with navigation links for 'FDA Home Page', 'CDRH Home Page', 'Search', 'CDRH A-Z Index', and 'Contact CDRH'. A secondary navigation bar lists various regulatory topics such as '510(k)', 'Registration', 'Listing', 'Adverse Events', 'PMA', 'Classification', 'CLIA', 'CFR Title 21', 'Advisory Committees', 'Assembler', 'Recalls', 'Guidance', and 'Standards'. The main search area is titled 'Search Registration Database' and includes links for 'Help', 'Download Files', and 'More About Registration'. It features four input fields: 'Establishment Name', 'Establishment Registration Number', and 'Owner/Operator Number', each with a corresponding text box. A 'Sort by' dropdown menu is set to 'Establishment Name (A-Z)'. A note below the fields states: 'For full-text search, select Go To Simple Search button'. At the bottom, there is a 'Go to Simple Search' button, a 'Records per Report Page' dropdown set to '10', a 'Search' button, and a 'Clear' button.

DUE DILIGENCE

➤ Does a current Device Listing exist for the device?

- Where the foreign manufacturer develops specifications, they should own the Device Listing. Where the U.S. entity develops specifications, they should own the Device Listing.
- Check FDA Website:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm>

The screenshot displays the FDA Center for Devices and Radiological Health website. At the top, the FDA logo and the text "U.S. Food and Drug Administration" are visible, along with the Department of Health and Human Services logo. Below this, the text "CENTER FOR DEVICES AND RADIOLOGICAL HEALTH" is displayed. A navigation bar contains links for "FDA Home Page", "CDRH Home Page", "Search", "CDRH A-Z Index", and "Contact CDRH". A secondary navigation bar lists various regulatory topics: "510(k)", "Registration", "Listing", "Adverse Events", "PMA", "Classification", "CLIA", "CFR Title 21", "Advisory Committees", "Assembler", "Recalls", "Guidance", and "Standards". The main section is titled "Search Device Listing Database" and includes links for "Help", "Download Files", and "More About Listing". The search form contains several input fields: "Proprietary Device Name", "Owner/Operator Name", "Owner/Operator Number", "Establishment Registration Number", "Product Code", and "Advisory Committee" (a dropdown menu). The "Sort by" field is set to "Device Name (A-Z)". Below the form, a note states: "For full-text search, select Go To Simple Search button". At the bottom, there are buttons for "Search", "Clear", a "Records per Report Page" dropdown set to "10", and a "Go to Simple Search" button.

DUE DILIGENCE

- **To what extent is compliance with FDA's Quality System Regulations (QSRs)/Good Manufacturing Practices (GMPs) required?**
 - GMP Exempt (recordkeeping and complaint file requirements still apply)
 - Full GMP Compliance

DUE DILIGENCE – Medical Device Reporting

- Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA
- Mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices
- Detect and correct problems in a timely manner
- Further information on the Medical Device Reporting process can be found at:
<http://www.fda.gov/cdrh/devadvice/351.html>

Medical Device Reporting for Manufacturer's

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
Manufacturer	30 day reports of deaths, serious injuries and malfunctions	Form FDA 3500A	FDA	Within 30 calendar days from becoming aware of an event
Manufacturer	5-day reports on events that require remedial action to prevent an unreasonable risk of substantial harm to the public health and other types of events designated by FDA	Form FDA 3500A	FDA	Within 5 work days from becoming aware of an event
Manufacturer	Baseline reports to identify and provide basic data on each device that is subject of an MDR report. At this time, FDA has stayed the requirement for denominator data requested in Part II, Items 15 and 16 on Form 3417.	Form FDA 3417	FDA	With 30 calendar, and 5 work day reports when device or device family is reported for the first time. Interim and annual updates are also required if any baseline information changes after initial submission.
Manufacturer	Annual Certification	Form FDA 3381	FDA	Coincide with firm's annual registration dates.

DUE DILIGENCE – U.S. Agent

- Foreign manufacturers must also designate a U.S. Agent.
- Information on U.S. Agents can be found at:
 - <http://www.fda.gov/cdrh/usagent/>



The screenshot shows the FDA website page for 'United States Agents for Devices'. The header includes the FDA logo and the text 'U.S. Food and Drug Administration' and 'CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'. Below the header are navigation links: 'FDA Home Page', 'CDRH Home Page', 'Search', 'CDRH A-Z Index', and 'Contact CDRH'. The main content area is titled 'United States Agents for Devices' and contains two sections: 'Identifying a United States Agent' and 'Interested in being a United States Agent'. Each section has a list of links: 'Background', 'Responsibilities of a United States agent', 'How to locate a United States agent', and 'How to notify FDA that I have retained a United States agent'.

FDA U.S. Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)

United States Agents for Devices

Identifying a United States Agent

- [Background](#)
- [Responsibilities of a United States agent](#)
- [How to locate a United States agent](#)
- [How to notify FDA that I have retained a United States agent](#)

Interested in being a United States Agent

- [Background](#)
- [Responsibilities of a United States agent](#)
- [How to enroll to offer my services](#)
- [When to update my enrollment as a United States agent](#)


Background

DUE DILIGENCE

Compliance History of Manufacturer

- What is the compliance history of the manufacturer, importer, and device?
 - **Warning Letters**
(www.fda.gov/foi/warning.htm)
 - **Recalls (Enforcement Report)**
(www.fda.gov/opacom/Enforce.html)

Sample Warning Letter

	JUN - 8 2007	Food and Drug Administration 2095 Galther Road Rockville MD 20850
WARNING LETTER		
VIA FEDERAL EXPRESS (AND FACSIMILE)		
Dr. Peter Schwind Managing Director Medion Diagnostics AG Bonnstrasse 9 CH-3186 Duedingen SWITZERLAND		
Dear Dr. Schwind:		
During an inspection of your firm located in Duedingen, Switzerland, on February 5, 2007, through February 8, 2007, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures The Sickie Sol Test and The Sickie Trol Sickie Cell Hemoglobin Controls. Under section 201(b) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.		
This inspection revealed that The Sickie Sol Test and The Sickie Trol Sickie Cell Hemoglobin Controls are adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). These devices are also misbranded under section 502(o) of the Act, 21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is available through the Internet at http://www.fda.gov/cdrh/devadvice/3122.html . The FDA will evaluate the information you submit and decide whether your product may be legally marketed.		
You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action, which may include detaining your devices without physical examination upon entry into the United States until the corrections are completed. Section 801(a) of the Act (21 U.S.C. § 381(a)). Also,		

DUE DILIGENCE

- **Is/has the device (been) subject to any of the following?**
 - Import Alerts – used to initiate automatic detentions of regulated products
(www.fda.gov/ora/fiars/ora_import_alerts.html)
 - Import Refusal Reports – view by country or product
(www.fda.gov/ora/oasis/ora_oasis_ref.html)

DUE DILIGENCE

Compliance History of Manufacturer

- Establishment Inspection Reports (EIRs)
 - EIRs are prepared by the FDA Investigator performing the inspection after every inspection.
 - This Report details the inspection and findings, and includes exhibits to document findings. EIRs are provided to the inspected entity following inspection.
 - They can be obtained in redacted form, by third-parties through a Freedom of Information (FOI) request.

DUE DILIGENCE

- Has a Notice of Sampling been received for the product?
 - *If yes* - hold the product intact and do not distribute until a "May Proceed" Notice is received.

Detention/Refusal Process

- Products that appear (from examination or otherwise) to be violative may be detained and ultimately refused entry into the U.S.
- The standard for detention and refusal is extremely low - detention is permissible without actual observation of a product or its labeling.
- The ability to challenge the FDA is limited almost exclusively to legal, as opposed to factual, issues.

Detention Process

Notice of FDA Action

- The Food, Drug, and Cosmetic Act (the Act) authorizes FDA to detain a regulated product that appears to be out of compliance with the Act.
- The FDA district office will then issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee.

Informal Hearing

- The owner or consignee is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product.

2nd Notice of FDA Action

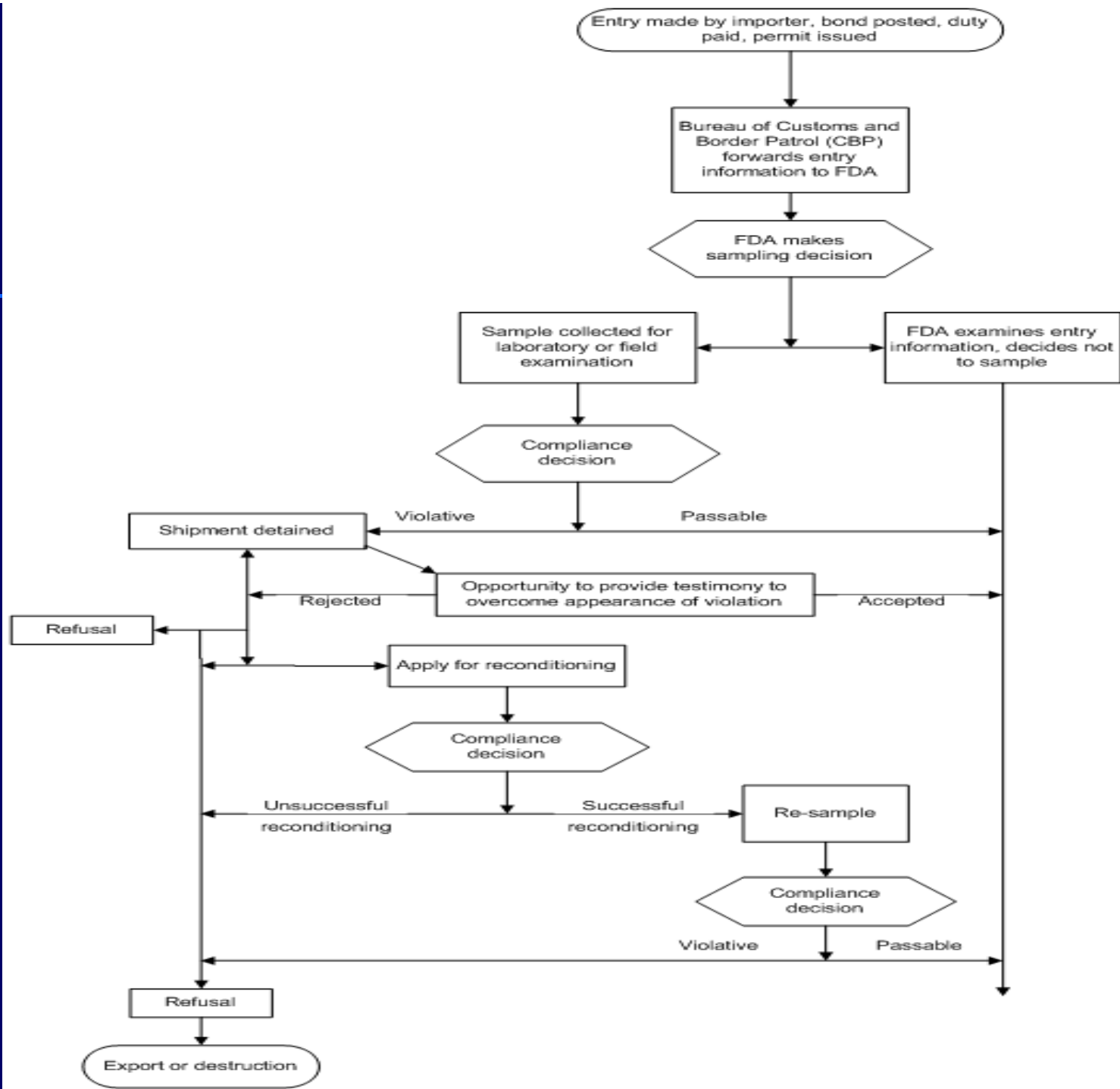
- If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another "Notice of FDA Action" Refusing admission to the product.

Refusal

- The product then has to be exported or destroyed within 90 days otherwise subject to Liquidated Damages.

Import Procedures Flowchart

- The next slide is an overview of the import process



Questions?

Peter Quinter, Shareholder

Best Practices For Importing Medical Devices

Board Certified Customs and
International Trade Attorney

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 - PQuinter@Becker-Poliakoff.com