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[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR880.2930]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart C--General Hospital and Personal Use Monitoring Devices

Sec. 880.2930 Apgar timer.

(a) *Identification.* The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 880.9. The device is also exempt from the current good manufacturing practice requirements in part 820 of this chapter, with the exception of 820.180 of this chapter, with respect to general requirements concerning records, and 820.198 of this chapter, with respect to complaint files.

[63 FR 59718, Nov. 5, 1998]

U.S. Food and Drug Administration

Medical Devices

Postmarket Requirements (Devices)

Medical device manufacturers as well as other firms involved in the distribution of devices must follow certain requirements and regulations once devices are on the market. These include such things as tracking systems, reporting of device malfunctions, serious injuries or deaths, and registering the establishments where devices are produced or distributed. Postmarket requirements also include postmarket surveillance studies required under section 522 of the act as well as post-approval studies required at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application.

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2009]
[CITE: 21CFR880.9]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart A--General Provisions

Sec. 880.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2318, Jan. 14, 2000]

U.S. Food and Drug Administration

Medical Devices

Device Registration and Listing

Device Registration and Listing: Get e-mail updates [1]

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution 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.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at "Who Must Register, List and Pay the Fee [2]". There are no reductions in annual establishment registration fees for small businesses or any other group

The schedule of registration fees for fiscal years as follows:

Year	FY 2008	FY 2009	FY 2010	FY2011	FY 2012
Fee	$1,706	$1,851	$2,008	$2,179	$2,364

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

The amendments to the Medical Device User Fee Modernization Act require that after September 30th, 2007, all registration and listing information be submitted electronically [3], unless a waiver [4] has been granted.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

Note: If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to reglist@cdrh.fda.gov.

Links on this page:

1. http://service.govdelivery.com/service/subscribe.html?code=USFDA_97
2. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm
3. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053156.htm
4. http://www.fda.govssLINK/ucm053185.htm#waiver

U.S. Food and Drug Administration

Medical Devices

Who Must Register, List and Pay the Fee

Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.) are required to register annually with the FDA. Most establishments that are required to register are also required to list the devices and the activities performed on those devices at that establishment.

The following charts detail the requirements for registration and listing based on the type of activity performed at that establishment. The chart also includes a column showing which types of activities require payment of the establishment registration fee. See the Fee page[1] for additional details.

- Domestic establishments
- Foreign establishments
- Definitions of establishment types

Domestic establishments

Activity	Register	List	Pay Fee
Manufacturer	YES 807.20(a)	YES 807.20(a)	YES
Manufactures a custom device	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES 807.20(a)(5)	YES 807.20(a)(5)	YES
Manufacturer of components that are distributed only to a finished device manufacturer	NO 807.65(a)	NO	NO
U.S. Manufacturer of export only devices	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Relabeler or Repackager	YES 807.20(a)(3)	YES 807.20(a)(3)	NO
Contract manufacturer who commercially distributes the device for the specifications developer	YES 807.20(a)(2),	YES 807.20(a)(2),	YES
Contract manufacturer who does NOT commercially distribute the device for the specifications developer	NO	NO	NO
Contract manufacturer of subassembly or component, Contract Packager or Labeler	NO	NO	NO
Contract sterilizer who commercially distributes the device	YES 807.20(a)(2),	YES 807.20(a)(2),	YES
Contract sterilizer who does NOT commercially distribute the device	NO	NO	NO
Kit Assembler	YES 807.20(a)	YES 807.20(a)	YES
Domestic Distributor	NO 807.20(c)(3)	NO	NO
Specification Developer	YES 807.20(a)(1)	YES 807.20(a)(1)	YES
Specification Consultant Only	NO	NO	NO
Initial Distributor/Importer	YES 807.40(a)	NO Enforcement Discretion Used for 807.22(c)	NO
Device being investigated under IDE	NO	NO 807.40(c)	NO
Reprocessor of single use devices	YES 807.20	YES 807.20	YES
Remanufacturer	YES	YES	NO
Maintains compliant files as required under 21 CFR 820.198 (Note: register as a manufacturer if physical manufacturing taking place at site, otherwise register as a specification developer)	YES	YES	YES

Foreign Establishments

Activity	Register	List	Pay Fee
Foreign Manufacturers	**YES** 807.40(a)	**YES** 807.40(a)	**YES**
Foreign Exporter of devices located in a foreign country	**YES** 807.40 (a)	**YES** 807.40 (a)	**NO**
Contract Manufacturer whose device is shipped to U.S. by the contract manufacturer or by any other firm	**YES** 807.40(a)	**YES** 807.40(a)	**YES**
Contract Sterilizer whose sterilized device is shipped to U.S. by the sterilizer or by any other firm.	**YES** 807.40(a)	**YES** 807.40(a)	**YES**
Reprocessor of Single-use Device	**YES** 807.20(a)	**YES** 807.20(a)	**YES**
Custom Device Manufacturers	**YES** 807.20(a)(2)	**YES** 807.20(a)(2)	**YES**
Relabeler or Repackager	**YES** 807.20(a)(3)	**YES** 807.20(a)(3)	**NO**
Kit Assembler	**YES** 807.20(a)	**YES** 807.20(a)	**YES**
Device Being Investigated under IDE	**NO** 812.1 (a)	**NO** 812.1(a), 807.40(c)	**NO**
Specification Developer	**YES**	**YES**	**YES**
Remanufacturer	**YES**	**YES**	**NO**
Manufacturer of components that are distributed only to a finished device manufacturer	**NO** 807.65(a)	**NO**	**NO**
Maintains compliant files as required under 21 CFR 820.198 (Note: register as a manufacturer if physical manufacturing taking place at site, otherwise register as a specification developer)	**YES**	**YES**	**YES**

Definitions of Establishment Activities

Contract Manufacturer - Manufactures a finished device to another establishment's specifications.

Contract Sterilizer - Provides a sterilization service for another establishment's devices.

Foreign Exporter - Exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.

Initial Distributor - Takes first title to devices imported into the U.S. An Initial Distributor must have a U.S. address.

Manufacturer - Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Repackager - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers).

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

Reprocessor of Single Use Devices – Performs remanufacturing operations on a single use device.

Specification Developer - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing. This includes establishments that, in addition to developing specifications, also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

U. S. manufacturer of export only devices – Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.

- Other FDA Registration Sites [2]

Links on this page:

1. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053186.htm
2. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/UCM056760

U.S. Food and Drug Administration

Medical Devices

How to Register and List

General Information

The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires that all registration and listing information (Annual, Initial or Updates) be submitted electronically unless FDA grants you a waiver.

- Registration and listing information is submitted by using FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM).
- To use FURLS, each owner/operator must have an account ID and password. If the owner/operator has designated another person to be the official correspondent, then the official correspondent may have a separate account ID and password.
- Firms who are already registered must use their already assigned account ID and password. You **SHOULD NOT CREATE a new FURLS account**. Creating a new account will prevent you from accessing your current registration information and delay the completion of your correct registration.
- If you have any questions on whether you have an established FURLS account, please contact us at reglist@cdrh.fda.gov.
- Assistance with resetting your password can be found on our website[2]. 053470
- If required to pay the user fee, it is a two step process[3]. 053186 First you must pay the fee. Then you can complete your registration. Your registration is not considered complete until you have paid your registration user fee, submitted your information electronically, and have received e-mail notification from FDA that all requirements have been met.
- If not required to pay the user fee, your registration is considered complete once you have submitted your information electronically and have received e-mail notification from FDA that all requirements have been met.

Annual Registration Instructions

1. Determine if your firm needs to pay the user fee. (See Who Must Register, List & Pay the Fee[4]). 053165
2. If required to pay, you must first pay the user fee by going to the Device Facility User Fee website[5]. If not required to pay, go to Step 4.
3. Make payment and obtain the Payment Identification Number (PIN) and the Payment Confirmation Number (PCN) before you complete your annual registration.
4. Go to https://www.access.fda.gov/oaa/[6] . Use your FURLS account ID and password to log on to the site.

If you are doing annual registration, you must already have an account ID and password. DO NOT CREATE A NEW ACCOUNT since this will prevent yo from accessing your current registration.

1. Select the DRLM button (Device Registration and Listing Module).
2. Select the "Annual Registration" link. **You must select the Annual Registration link and complete that process in order for your establishment to be considered registered for the current fiscal year.** Selecting this Annual Registration link will also allow you to update your information.
3. Review the registration information for your establishment and make any updates.
4. Everyone (except initial distributors) must also review their listing information and make updates, if needed.
5. Certify that all the information is correct and click on the submit button.
6. If not required to pay, your registration should be complete and you will receive e-mail notification confirming your registration for the current fiscal year from FDA.
7. If required to pay the user fee, you will be prompted to enter both the PIN and PCN numbers. This information must be entered in order for FDA to accept your registration. If you are required to pay the fee and are not prompted for the PIN/PCN number, please send an email to reglist@cdrh.fda.gov. Without entering these numbers, your registration is incomplete.

Annual Registration for Firms Without a Registration Number

Information is available at:

- Annual Registration for Firms Without a Registration Number[7]

Initial Registration

1. Determine if your firm needs to pay the user fee. (See Who Must Register, List & Pay the Fee[8]) 053165
2. If required to pay, you must first pay the user fee by going to the Device Facility User Fee website[9]. If not required to pay, go to Step 4.
3. Make payment and obtain both the Payment Identification Number (PIN) and Payment Confirmation Number (PCN).
4. Go to https://www.access.fda.gov/oaa/[10] .

5. If you have never previously submitted an establishment registration, you will need to first create a FURLS account for the owner/operator (Se Types of FURLS Accounts below). **Note**: If you already have an account for this owner/operator, you should log on to FURLS using that user IC and password.
6. Once you have set up the FURLS account ID and password, select the DRLM button (Device Registration and Listing Module).
7. Select the link "Register a Medical Device Facility".
8. Enter information about your facility and select "Continue Registration"
9. Create Listings for devices produced or processed at this facility. All facilities are required to list devices except Initial Distributors.

For each listing, you will need to identify whether your product requires premarket notification/approval or is exempt.

If a device requires premarket notification clearance or approval it can ONLY be listed AFTER the premarket submission [510(k), PMA, etc.] is cleared or approved. If this is your only device listing, please do not register your establishment until after your premarket submission is cleared or approved.

If your premarket submission is cleared or approved, you will need to do the following to list your device:

- Enter the premarket submission number
- Enter the proprietary name(s)
- Identify the activities that you perform on or to the device

If your device is exempt from premarket notification/approval, you will need to do the following:

- Identify the product code (prior to logging into FURLS)
- Leave the premarket submission number blank
- Enter the product code in the filter box and click on "Filter"
- Select the radio button next to the product code and click "Continue"
- Identify the activities that you perform on or to the device
- Enter the proprietary name(s)

1. Certify that all the information is correct and click on the submit button.
2. If not required to pay, your registration should be complete and you will receive an e-mail notification confirming your registration for the current fiscal year from FDA.
3. If required to pay the user fee, you will be prompted to enter the payment-related numbers (PIN/PCN). This information must be entered for FDA to accept your registration. If you believe that you are required to pay and you are not prompted for the PIN/PCN number, please send an email to reglist@cdrh.fda.gov. Without these numbers, your registration is incomplete.

Types of FURLS Accounts

There are two types of accounts in FURLS: owner/operator and official correspondent:

An owner/operator is defined as:

- The corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registered establishment.

The owner/operator can:

- Create and update all of the official correspondents' FURLS accounts, including their own account(s)
- Assign official correspondents to registrations
- Create new registrations and listings
- Make changes, updates and cancellations to registrations and listings that they created
- View registration and listing information for the establishments that they created
- View all non-exempt listings belonging to the owner/operator that must be replaced

You will also be required to create a sub-account for any official correspondents you identify.

An official correspondent is defined as:

- The person designated by the owner/ operator of an establishment responsible for the annual registration of the establishment and the device listing. The official correspondent also receives correspondence from the FDA involving the owner/operator and any of the firm's establishments.

The official correspondent is responsible for the registration and listing information for each establishment to which he/she is assigned.

The official correspondent can:

- Create new registrations and listings
- Make changes, updates and cancellations to registrations and listings that have been assigned to them
- Add their establishment(s) to listings previously entered for the owner/operator
- View registration and listing information for the establishments which have been created by or assigned to them

Updating Owner/Operator and Official Correspondent Account Information

To update the owner/operator's account infor mation:

1. Log into FURLS using the owner/operator account id and password.
2. Click on "Edit Profile".
3. Select the radio button next to "Account" to modify the owner/operator's information. If you are both the owner/operator and official correspondent for the facility, then you will only see one "Account" when you click on "Edit Profile". If you have designated a person to be the official correspondent for the facility, then you will see "Account" and "Sub-Account" when you click on "Edit Profile".
4. Click on "Modify".
5. Make any necessary changes to the account and click "Submit". Any changes you make to the owner/operator account will be reflected in the Owner/Operator Infor mation for the facility.

To update the official correspondent's account infor mation:

1. The owner/operator must log into FURLS using the owner/operator account id and password.
2. Click on "Edit Profile".
3. Select the radio button next to "Sub-Account" to modify the official correspondent's infor mation.
4. Click on "Modify".

5. Make any necessary changes to the account and click "Submit". The changes you make will auto matically be reflected in the official correspondent's infor mation for the facility.

To create new subaccounts for official correspondents:

(If you change the official correspondent of facility and create a new subaccount for this official correspondent, then you will need to do the following steps to update the official correspondent for the facility)

1. Click on "Device Registration and Listing"
2. From the main menu, select "Change Official Correspondent for a Facility" and click "Continue"
3. Check the box next to the facility that you want to change the official correspondent for and click "Continue"
4. Select the box next to the new official correspondent and click on "Continue"
5. Review the change and click on "Submit".

Updating Registration and Listing Information

1. Updates to Registration and Listing information can be done at any time. Updating your information may change whether you are required to pay the establishment registration user fee. You will need to determine if your firm needs to pay the user fee. (See Who Must Register, List & Pay the Fee [11]). 053165
2. If required to pay, you must first pay the user fee by going to the Device Facility User Fee website [12]. If not required to pay, go to Step 4
3. Make payment and obtain both of the payment-related numbers (PIN and PCN) before you can make any updates to your information. Note: Once you have paid the user fee for an establishment for a fiscal year, you may continue to make changes in the listings of that establishment during the fiscal year without an additional charge.
4. Go to https://www.access.fda.gov/oaa/ [13]. Use your FURLS account ID and password to log on to the site. DO NOT CREATE A NEW ACCOUNT.
5. Select the DRLM button (Device Registration and Listing Module).
6. Select the "Change Registration" link to update registration information or select the "Change, Cancel or Reactivate Listing" link to update your listing information.
7. Make the necessary changes to your registration or listing information
8. Review the changes you have made.
9. Certify that all the information is correct and click on the submit button.
10. If not required to pay, your registration should be complete and you should receive an e-mail notification confirming your registration for the current fiscal year from FDA.
11. If required to pay the user fee, you will be prompted to enter payment-related numbers (PIN/PCN). This information must be entered for FDA to accept your registration. If you believe that you are required to pay and you are not prompted for the PIN/PCN number, please send an email to reglist@cdrh.fda.gov. Without these numbers, your registration is incomplete.

Waivers

The law requires that all registration and listing information be submitted electronically unless FDA grants a waiver. To apply for a waiver from submitting your registration and listing information electronically, please submit your request with a complete explanation of why you cannot submit your information electronically to:

Food and Drug Administration
CDRH - Office of Compliance
Registration & Listing
10903 New Hampshire Avenue
Building 66 Room 2621
Silver Spring, MD 20993-0002

Note: If you are granted a waiver, you will still be responsible for the establishment registration fee (if required to pay).

Links on this page:

1. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053426.htm
2. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053470.htm
3. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053186.htm
4. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm
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6. http://www.fda.govhttps://www.access.fda.gov/oaa/
7. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053426.htm
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