

Patty Irish

From: Bill Stenger (bstenger@jaypeakresort.com)
Sent: Thursday, June 03, 2010 7:32 AM
To: pirish@jaypeakresort.com
Subject: Fw: FDA: Medical Device Regulatory Requirements
Attachments: General Requirements - Medical Device Ltr.pdf

Bill Stenger
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-----Original Message-----

From: "Velez Cabassa, Aileen" <Aileen.VelezCabassa@fda.hhs.gov>
Sent 6/2/2010 2:26:56 PM
To: bstenger@jaypeakresort.com
Cc: "CDRH Small Manu. Assistance" <DSMA@CDRH.FDA.GOV>
Subject: FDA: Medical Device Regulatory Requirements

Dear ~~Bill~~, Bill:

As per our telephone conversation here is the information to help understand the medical device regulation.

Medical devices are classified into Class I, II, and III. 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 Premarket Notification (510(k)); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval (PMA). A description on how to market your device is available on our website at:
<<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>> ..

Classification

To determine a devices classification you will have to search our Classification database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> to search for a predicate device. If there is a predicate device the database will provide you the Product Code and links to the Guidance to follow. Enter general terms when you perform a search and go through the list to determine which best fits your product.

If you know of a manufacturer or the name of a device available in the U.S. market you can search our "Registration and Listings" database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>. This can help you determine the classification and product code for your device and you can now go back to the Classification database and perform a search for the product code.

513(g)



Questions concerning the classification of a device or the regulatory requirements applicable to a device can be submitted, via the mail only, to the FDA . The request is authorized under Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act). There is a nominal fee associated with the submission of a 513(g) request. Here is a link with information on how to make the request <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127147.htm>.

SBD

FDA's "FY 2010 Medical Device User Fee Small Business Qualification and Certification" guidance is available online at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM179257.pdf>. This guidance explains how your business may qualify as a "small business" and pay most FY 2010 medical device user fees at substantially discounted rates; if you qualify as a small business. This includes a reduced fee for a 513(g) request.

There is no discounted small business fee for the required annual establishment registration fee; every establishment that is required to pay the annual registration fee will pay the same fee. For fees please review the following links <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109177.htm>.

Regulatory Requirements

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:

- * Establishment registration
- * Medical Device Listing
- * Premarket Notification 510(k) , unless exempt, or Premarket Approval (PMA),
- * Investigational Device Exemption (IDE) for clinical studies
- * Quality System (QS) regulation
- * Labeling requirements , and
- * Medical Device Reporting (MDR)

Attached is a letter with weblinks that will to help you understand the requirements . You can also visit us at CDRH Learn. It is our latest innovative educational tool which consists of a series of training modules describing many aspects of medical device and radiological health regulation, covering both premarket and postmarket issues. Here is the link to CDRH Learn <http://www.fda.gov/Training/CDRHLearn/default.htm>.

Aileen I. Velez Cabassa, M.S.
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Division of Small Manufacturers, International and Consumer Assistance (DSMICA)
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This response represents to the best of my judgment how the device should be regulated, solely based upon a review of the information you have provided. This response is not a classification decision for your device and does not constitute FDA clearance or approval for commercial distribution. Unless exempt from premarket notification submission (510(k)) requirements, the official classification for your device will appear on the final decision letter from any premarket review. All device types

classified as exempt from the 510(k) requirements are subject to the limitations of exemptions. Limitations of device exemptions are found in the device classification chapters in 21 CFR xxx.9, where xxx refers to Parts 862-892 (e.g., 862.9, 864.9, etc.). Please be aware, if I have indicated that I believe your device falls within a device category classified as exempt from premarket review requirements, that it is your responsibility to ensure that you meet the exemption criteria and your device does not exceed the limitations of exemption. If your device exceeds the limitations of exemption, you must submit a 510(k) and receive a letter from FDA stating that your device may be commercially distributed in the U.S. prior to marketing your device.

This communication is consistent with 21 CFR 10.86 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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Patty Irish

From: Bill Stenger [bstenger@jaypeakresort.com]
Sent: Thursday, June 03, 2010 7:34 AM
To: pirish@jaypeakresort.com
Subject: Fw: FDA: Pre-IDE Meeting Request

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-----Original Message-----

From: "Velez Cabassa, Aileen" <Aileen.VelezCabassa@fda.hhs.gov>
Sent: 6/2/2010 2:45:41 PM
To: bstenger@jaypeakresort.com
Cc: "CDRH Small Manu. Assistance" <DSMA@CDRH.FDA.GOV>
Subject: FDA: Pre-IDE Meeting Request

Hi Bill—I did not provide you the information on requesting a meeting with the FDA in my previous email but here it is...

If your interested in coming in to the FDA to discuss your device you can request to set up an early collaboration meeting. Here is the guidance on requesting the meeting;
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073604.htm>. The meeting will include reviewers from the Office of Device Evaluation (ODE) who are experts reviewing your type of product to discuss the requirements.

To proceed with setting up a preIDE meeting, we request that you officially submit a preIDE package (minimum of 2 copies required) to the Agency. Upon receipt of the preIDE information, we can proceed with setting up a mechanism to discuss the issues of interest to you. Again, the Agency typically tries to provide feedback (either through meeting, email, phone, etc.) within a 60-day timeframe; however, please note that this is not a MDUFMA deadline.

Please feel free to contact me if you need any further assistance.

Aileen I. Velez Cabassa, M.S.
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device does not exceed the limitations of exemption. If your device exceeds the limitations of exemption, you must submit a 510(k) and receive a letter from FDA stating that your device may be commercially distributed in the U.S. prior to marketing your device.

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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