

Introduction and Regulatory Reference Sheet
Orthopedic and Rehabilitation Devices Panel
May 21, 2013

On May 21, 2013, the Orthopedic and Rehabilitation Devices Panel (the panel) will discuss and make recommendations regarding shortwave diathermy (SWD) devices that do not apply therapeutic deep heat, referred to as nonthermal SWD, for certain uses.

This device type is a pre-Amendment Class III device, meaning that this device type was marketed prior to the Medical Device Amendments of 1976 and was classified by the original classification panels as Class III, but FDA did not establish an effective date for the requirement for premarket approval (PMA). As a result, this device may proceed to market via the premarket notification [510(k)] process until such time as the classification steps are completed.

On April 9, 2009 (74 FR 16214), the FDA issued an order in the Federal Register (available under Docket No. FDA-2009-M-0101 on www.regulations.gov) requiring safety and effectiveness information for this device type to determine whether the classification should be revised to require a PMA application or whether the device should be down-classified into Class I (General Controls) or Class II (General and Special Controls).

At this meeting, the panel will be asked to discuss the classification of nonthermal SWD devices. The panel will be asked to discuss the cleared indications, the risks to health, the available safety and effectiveness information and potential special controls.

After this advisory panel meeting, the FDA will consider all available scientific evidence and the input from panel members in determining whether to require PMA applications for nonthermal SWD devices or down-classify them into Class II or Class I. The FDA will then publish a proposed order announcing the agency’s intentions, which will be open for a public comment period. After consideration of all additional comments received, the FDA will intend to proceed with issuance of a final order to finalize the classification process for nonthermal SWD devices, which will identify the FDA’s final classification for this device type.

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What data should be considered when making a classification recommendation?

Initial classification and reclassification decisions are based on existing information for legally marketed devices and their predicates. Although information on future technology or new indications applicable for these devices may be available, this information is not relevant to the deliberations of the panel. The panel must consider only the legally marketed cohort of the device type in question.

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What are the definitions of Class I, Class II and Class III?

Federal law (Federal Food, Drug, and Cosmetic Act, section 513), established the risk-based device classification system for medical devices. Each device is assigned to one of three regulatory classes: Class I, Class II or Class III, based on the level of control necessary to provide reasonable assurance of its safety and effectiveness.

As device class increases from Class I, to Class II to Class III, the regulatory controls also increase, with Class I devices subject to the least regulatory control, and Class III devices subject to the most stringent regulatory control.

The regulatory controls for each device class include:

- Class I (low to moderate risk): General Controls
- Class II (moderate to high risk): General Controls and Special Controls
- Class III (high risk): General Controls and Premarket Approval (PMA)

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Class I, General Controls

A device is Class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Examples of general controls are: registration and listing, medical device reporting, labeling, and good manufacturing practices (GMPs). Devices may also be considered Class I if the device “is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and does not present a potential unreasonable risk of illness or injury.”¹ Most Class I devices are exempt from submitting a 510(k). Examples of Class I devices include general manual orthopedic surgical instruments, adhesive bandages, manual wheelchairs, and crutches.

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Class II, General and Special Controls

A Class II device is “a device which cannot be classified as a Class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.”² Examples of special controls are: performance standards, postmarket surveillance, patient registries, special labeling requirements, and development and dissemination of guidelines. Special controls may also include specific types of performance testing (e.g., biocompatibility, sterility, electromagnetic compatibility, pre-clinical or clinical testing) or labeling, which FDA may outline in the regulation or a special controls guideline. Most Class II devices require clearance of a 510(k) prior to marketing. Sponsors are required to submit valid scientific evidence in their 510(k) demonstrating that the device is as safe and effective as a predicate device. Companies submitting a 510(k) for a device must demonstrate how any specified special controls have been met in order to receive marketing clearance. Examples of Class II devices include powered wheelchairs, intervertebral fusion devices (i.e., cages), resorbable calcium salt bone void fillers, and powered muscle stimulators.

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Class III, General Controls and Premarket Approval

A Class III device is a device which:

1. “cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device,” **and**
2. “cannot be classified as a class II device because insufficient information exists to determine that the special controls...would provide reasonable assurance of its safety and effectiveness,” **and**
3. “is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,” **or**

¹ See Section 513(a)(1)(A) of the Food, Drug and Cosmetic (FD&C) Act.

² See Section 513(a)(1)(B) of the FD&C Act.

4. “presents a potential unreasonable risk of illness or injury.”³

Class III devices require premarket approval prior to marketing the device and must provide valid scientific evidence to demonstrate that the device has demonstrated a reasonable assurance of safety and effectiveness through the submission of a PMA application. Examples of Class III devices include stair climbing wheelchairs, total artificial disc replacements, and implanted neuromuscular stimulators.

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What will the panel be asked to consider in determining which device class to recommend?

Risks to Health

The FDA will present the risks to health that they have identified to be associated with use of nonthermal SWD devices. Some of these risks to health may have been identified by previous classification panels and some may have been identified by FDA and/or comments received through associated rules or orders. The panel will be asked to comment on whether they disagree with inclusion of any of the identified risks or whether they believe any other risks should be considered.

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Safety and Effectiveness

The FDA will present available information regarding the safety and effectiveness of nonthermal SWD devices as it relates to the cleared indications for use and technology. The panel will be asked to comment on the adequacy of the available scientific evidence with respect to safety and effectiveness for these devices and to determine whether the probable benefits to health from use of the devices for specific indications outweigh the probable risks. If safety and/or effectiveness information are not established for nonthermal SWD devices, or for specific indications or technology of the device type, PMAs should be requested to demonstrate a reasonable assurance of safety and effectiveness.

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Special Controls

The FDA will present proposed special controls for those indications or technologies that they believe have established a reasonable assurance of safety and effectiveness. The panel will be asked to comment on the adequacy of these proposed special controls in providing a reasonable

³ See Section 513(a)(1)(C) of the FD&C Act.

assurance of safety and effectiveness in light of the available scientific evidence. The panel will also comment on whether any additional special controls should be proposed. If special controls can mitigate the identified risks to health, and safety and effectiveness have been established, it would be appropriate to recommend down-classification of the device types to Class II, special controls.

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What is a “reasonable assurance of safety”?

As defined in 21 CFR 860.7(d)(1), “There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.”

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What is a “reasonable assurance of effectiveness”?

As defined in 21 CFR 860.7(e)(1), “There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.”

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What are the practical implications of maintaining this device type in Class III?

If FDA issues a final order classifying nonthermal SWD devices, or portions of this device type, into Class III, companies wishing to continue to market existing devices of this type must file a premarket approval (PMA) application within the specified timeframe that is designated in the final classification order. To support approval, the information in the PMA (including clinical data) would have to demonstrate a reasonable assurance of safety and effectiveness. New devices or changes to existing devices would require approval of a PMA or PMA supplement. If a company does not file a PMA within the specified timeframe or otherwise does not receive an approval order for their product, the products are considered to be misbranded and should be removed from the market.

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What happens if FDA decides to down-classify this device type into Class II?

If nonthermal SWD devices, or portions of this device type, are down-classified, these devices would continue to be subject to the premarket notification (510(k)) requirements, but would also be subject to any special controls specified in the final classification order. New devices and changes to existing devices that require a new submission to FDA would require a 510(k) that demonstrates substantial equivalence and that the special controls have been met.

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What are the practical differences between PMA (Class III) and 510(k) (Class II) requirements?

A PMA application must provide all evidence to independently demonstrate a reasonable assurance of safety and effectiveness of the device. PMAs typically involve data from clinical trials of the specific device that support both safety and effectiveness, as well as detailed manufacturing information for the device. Conversely, a 510(k) submission can leverage existing information on predicate devices, including applicable clinical data, to support marketing clearance. For devices subject to 510(k), the premarket submission need only provide evidence that the device has indications and technological characteristics consistent with existing legally marketed predicate devices and meets any required special controls.

Once a PMA is approved, the PMA holder must report all design, manufacturing, and labeling changes made to the approved device to FDA via PMA supplements⁴ and PMA annual reports.⁵ PMA holders are also typically subject to ongoing postmarket requirements, whereas postmarket oversight is not as stringent for 510(k) holders. For example, for 510(k) devices, companies do not need to submit many types of minor changes to a device or its labeling to FDA for review, nor do they need to submit manufacturing changes or annual reports.

Regardless of the classification of these device types, FDA does not regulate the practice of medicine, specifically, which devices clinicians can use and how they use them.

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⁴ Refer to FDA's Guidance for Industry and FDA Staff: 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080192.htm>).

⁵ Refer to FDA's Draft Guidance for Annual Reports for Approved Premarket Approval Applications (PMA) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089381.htm>).

Why is this device type in the most stringently regulated Class III classification, but currently reviewed by FDA via the premarket clearance (510(k)) process?

When FDA's medical device regulation program began in the late 1970s, FDA regulated over 170 Class III device types through the 510(k) program. The intent was that FDA's regulation would be temporary and that, over time, FDA would decide to reclassify those device types (or regulations) into Class I or II, or to sustain the classification in Class III and call for PMA applications. Over the years, FDA has made progress in this original list; however, as of 2009, 26 medical device classification regulations, including the classification regulation for nonthermal SWD devices, remained in this transitional state awaiting final classification. This panel meeting is the result of FDA's ongoing 515 Program Initiative to facilitate the final adjudication of these remaining Class III device types. Based on recent legislative changes made to the Federal Food, Drug and Cosmetic Act through the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, FDA is now required to hold a meeting of a device classification panel prior to finalizing the reclassification of a device type. FDA is seeking panel input on nonthermal SWD devices to inform FDA's recommendation regarding the appropriate regulatory classification for this device type.

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May I recommend a final classification of Class I or Class II, even if the device is eligible for Class III?

Although a device may be eligible for classification as a Class III device, you may still find that there is sufficient information (valid scientific evidence) to determine that general controls alone (Class I), or general controls and the application of special controls (Class II), can provide reasonable assurance of safety and effectiveness of the device. If this is the case, then you may recommend that the device be classified into a class other than Class III. In this scenario, then you should provide a rationale that summarizes the valid scientific evidence supporting your recommendation, and identifies the controls you believe are sufficient to provide reasonable assurance of safety and effectiveness.