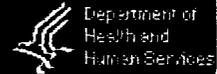


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## 515(i) Reclassification Letter to Manufacturers

April 30, 1998

510(k) Number:

Received:

Product:

Dear Sir/Ms:

The Food and Drug Administration (FDA) is continuing its implementation of the provisions of the Safe Medical Devices Act of 1990 (SMDA) which address preamendments devices classified in Class III. FDA is now seeking information from you to determine if down classification, from Class III to Class II or Class I, is appropriate for certain of these devices. When requested under Section 515(i) of the Food, Drug and Cosmetic Act (the Act) all manufacturers may be called to submit a summary of, and a citation to, updated safety and effectiveness data, including any adverse information, to the FDA.

Based upon a review of this information, FDA will then initiate a reclassification action for the device or call for premarket approval applications (PMA's) for the device. A list of these devices, and the deadlines for submission of updated safety and effectiveness information, were published in the Federal Register on August 14, 1995 (copy enclosed). FDA records indicate that you manufacture/market one of these devices and are required to submit the summary described above.

When FDA decides to reclassify the device or to request a PMA application, the action applies to the entire class of devices, not just the specific device(s) that you manufacture. In our experience there is some benefit to both manufacturers and FDA when manufacturers collaborate and submit a single document for review. A group can be organized through a trade association or other organization by contacting other manufacturers of the device for which reclassification is sought. However, FDA will review, and base its decision on, all submissions (single or group submissions) received pertaining to a device type.

Background information on the reclassification process and the requirements under 515(i) is enclosed along with a suggested format to be used in preparing your submission. Please bear in mind that submitting complete and accurate information will help FDA in reaching a decision on reclassifying a device. A lead reviewer has been assigned for each device, to coordinate review of your submission within the division.

Name of Device. SEE ATTACHMENT A

Expected date of submission: August 14, 1998

Name of lead reviewer: SEE ATTACHMENT A

Send one original and two copies of your submission to:

Document Mail Center, HFZ-401  
515(i) Submission  
Center for Devices and Radiological Health

9200 Corporate Blvd.  
Rockville, MD 20850

At this time, electronic submissions will be accepted with prior approval of the lead reviewer and accompanied with the required hard copies (one original and two copies)

Please note that the Center for Devices and Radiological Health intends to upload this letter on the World Wide Web FDA HomePage under new items at the following address:

<http://www.fda.gov/cdrh/newpg.html>

We recognize that the reclassification process is new to many manufacturers, and hope that the background information enclosed is helpful. We also extend our appreciation to the manufacturers that responded to the October 20, 1997 request for information for their devices

Please contact Doreen M. Melling, Reclassification Coordinator at 301 594-2186 or the lead reviewer named above with any questions.

Sincerely yours,

Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

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**BACKGROUND INFORMATION ON RECLASSIFICATION AND 515(i) SUBMISSION**

**Definition of Devices**

The Medical Device Amendment of 1976 and the Safe Medical Device Act of 1990 (SMDA) define three classes of devices in Section 513(a)(1).

**Class I** includes devices for which general controls alone are sufficient to assure safety and effectiveness for their intended use. General controls are sections 501 (no adulterated devices), 502 (no misbranded devices), 510 (registration, listing and premarket notification), 516 (no banned devices), 518 (notification), 519 (records reports and MDR's), and 520(f), GMP's).

**Class II** includes devices for which 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 including performance standards, voluntary standards including those promulgated by groups such as AAMI or ANSI, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions, known as 510(k)'s), recommendations, user checklists, and other appropriate actions. Class II devices are subject to all general controls as well as special controls.

**Class III** are devices for which insufficient information exists to assure that general controls (Class I) and special controls (Class II) provide reasonable assurance of safety and effectiveness, **and** if the devices are those represented to be life sustaining or life supporting, or for use which is of substantial importance in preventing impairment of human health or present potential unreasonable risk of illness or injury. Generally, implanted devices have been placed in Class III unless a lower class can be justified by sufficient information to promulgate special controls or a performance standard. New devices after 1976 and transitional devices considered drugs prior to 1976 are classified into Class III by statute

### **Original Classification Process**

When these devices were originally classified in the late 1970's and early 1980's, the Classification Panels identified certain risks to health which became the basis for classifying these devices into Class III (premarket approval). Based on the information available at the time, the Panel believed these risks could not be controlled by either general controls or performance standards.

### **Known Potential Benefits**

After addressing all of the identified risks, the reviewer should summarize the *known potential benefits* of the device. The purpose of this summary is to support the conclusion that, in light of the proposed special controls, there is reasonable assurance that the device is safe and effective for its intended use.

### **Special Controls**

As stated previously, Special Controls are those tests or other assessments that allow the FDA to review devices with premarket notification (510(k)) submissions with reasonable assurance of device safety and effectiveness when general controls are not sufficient. Examples include performance standards (including voluntary standards), FDA guidance documents, device labeling, and post-market surveillance.

Please list special controls currently in place for the device, and propose any additional ones that you

feel are appropriate.

### **Recommendation**

Provide a statement recommending reclassification of the device into Class I or Class II, or continuation of Class III.

### **Summary or Valid Scientific Evidence and Reasons for Recommendation**

Provide a summary of reasons why the device meets the criteria for the Class recommended above. This should include valid scientific evidence, reasonable assurance that the device can be used safely and effectively for its intended use in light of general and special controls.

The term *new information*, as used in § 513(e) and defined in this document, must consist of *publicly available, valid scientific evidence*. As stated in § 860.7(c), information from all of the following sources can and should be used when determining the safety and effectiveness of a device for the purpose of considering device class:

- well-controlled investigations,
- partially-controlled studies,
- studies without matched controls,
- well-documented case histories conducted by qualified experts, and
- reports of significant human experience.

All of the above sources of valid scientific evidence pertain to clinical as well as non-clinical data, and may include information presented by the Panel at an advisory panel meeting. The level of valid scientific evidence required for the proposed rule should reflect the significance and complexity of the specific safety and effectiveness issues being addressed with the particular device.

### **SMDA 1990 and Special Controls**

The Safe Medical Devices Act (SMDA) of 1990 has now changed the definition of Class II devices. SMDA states that Class II devices are those devices for which there is not enough information to show that general controls *alone* will assure safety and effectiveness, but there is sufficient information to establish "special controls" to provide such assurance. Instead of only performance standards, FDA may now use special controls such as specific labeling, FDA guidance document, and postmarket surveillance. SMDA allows FDA to use a wider range of controls to manage the risks that cannot otherwise be addressed by general controls- SMDA, in effect, broadens the applicability of Class II.

In order to reclassify a device into Class II, the FDA must be shown that *general and special controls* are available to reasonably assure the device's safety and effectiveness.

### **Reclassification**

The following should be included in your 515(i) submission to the FDA:

#### **Device Description**

Provide a concise description of the device and its indication(s) for use, including the principle of operation. This description should be sufficiently detailed to distinguish the

device from other devices that would not be considered substantially equivalent. When preparing this section, it is helpful to consult the description of the generic device class stated in the Code of Federal Regulations (CFR).

### **Risks to Health**

Each of the major risks to health presented by the device should be separately summarized.

Risks may be identified from:

1. The proposed and final classification rules (based on the Classification Panel's recommendation)
2. Review of the literature
3. Review of the MDR's
4. Labeling for the device

For each of the identified risks please provide a summary of the following information:

1. The incidence rate
2. Cause
3. Sequelae of the risk
4. Information demonstrating that the stated risk is not a potential hazard of the device, if available.

Much of the information required for writing this section may be obtained through a detailed literature search. Please cite any applicable published articles or panel recommendation/transcripts.

### **Bibliography and References**

Bibliography and copies of all reference cited including published literature, Federal Register documents, MDR and existing standards.

### **SUGGESTED FORMAT FOR SUBMISSION OF 515(i) DOCUMENTS TO FDA (If you Think Reclassification is Appropriate)**

- I. Description of device
  - A. Describe your device in detail
  - B. Describe the range of devices you think should be included in the reclassification.
  - C. Intended use(s) of the device
- II. For each specific risk posed by the device, please provide a separate section including:
  - A. Describe risk of device
  - B. Incidence rate
  - C. Cause
  - D. Sequelae of risk
- III. Special controls to address risks described above

- A. List special controls currently in use
- B. Propose special controls that could be applied

- IV. Potential Benefits of the device
- V. Recommendation for class
- VI. Summary of valid scientific evidence supporting recommendation
- VII. MDR Experience
- VIII. Bibliography of published literature

### **SUGGESTED FORMAT FOR SUBMISSION OF 515(i) DOCUMENTS TO FDA**

(If you think the device should remain in Class III and a call be made for PMA's)

- I. Description of device
  - A. Description of device
  - B. Intended use(s)
- II. Summary of other device labeling
- III. Summary of risks including MDR's
- IV. Summary of alternative practices and procedures
- V. Summary of preclinical and clinical data
- IV. Bibliography

### **ATTACHMENT A**

<u>Device Name</u>	<u>LEAD REVIEWER</u>	<u>DIVN</u>	<u>TEL #</u>
Pacemaker repair or replacement material	Mitch Shein	DCRND	301-443-8517
External cardiac compressor	Carroll O'Neill	DCRND	301-443-8262
	Steve Hinckley	DGRD	301-594-1296

Cranial Electrotherapy Stimulators

Implanted blood access device

Gema Gonzalez

DREARD 301-594-1220

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*Updated May 6, 1998*

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