

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
SUPPLEMENTAL DATA SHEET

FORM APPROVED: OMB NO. 0918-0138
 EXPIRATION DATE: January 31, 2003
 (See OMB Statement on Page 2)

Panel Recommendation

1. GENERIC TYPE OF DEVICE Non-invasive Bone Growth Stimulator	
2. ADVISORY PANEL Orthopedic and Rehabilitation Devices Panel	3. IS DEVICE AN IMPLANT (21 CFR 860.3)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4. INDICATIONS FOR USE IN THE DEVICE'S LABELING The device is intended for use for 1) the treatment of established nonunion fractures acquired secondary to trauma (excluding vertebrae and flat bone); and 2) as an adjunct to the treatment of lumbar spinal fusion surgery for one or two levels.	
5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE General Electrical Shock Burn Skin Irritation and/or Allergic Reaction Inconsistent or Ineffective Treatment	
6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY Classification <u>Class II (Special Controls)</u> Priority (Class II or III Only) _____	
7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA Not applicable	
8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED The petitioner conducted a literature search to describe the benefits and risks of the Non-invasive Bone Growth Stimulator. The literature available on the Non-invasive Bone Growth Stimulator is comprehensive and establishes the benefits of device use for nonunions and as adjunct to lumbar spinal fusion. The literature review also establishes that the risks associated with the device do not present an unreasonable risk of illness or injury. The identified adverse events are typically transient, rarely meeting the definition of a serious injury, and can be addressed by either terminating or modifying device usage. Further, the failure modes for these devices are well-understood, allowing for the application of Special and General Controls to provide for a reasonable assurance of safety and effectiveness.	
9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, banning, or prescription use) Prescription use	

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- a. Registration / Device Listing _____
- b. Premarket Notification _____
- c. Records and Reports _____
- d. Good Manufacturing Practice _____

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- a. Exempt
- b. Not Exempt

Justifications/Comments

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (*Components*) OR DEVICE MATERIALS (*Parts and Accessories*)

21 CFR Part 898 Performance Standards for Electrode Lead Wires and Patient Cables
ISO 10993: Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing
IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1-2: Electromagnetic Compatibility for Medical Equipment: Requirements and Tests

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

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