



AUG 12 2005

3 1 8 4 5 AUG 18 A 9 :36

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William Carroll  
Vice President, Research and Development  
RS Medical  
14404 SE First Street  
Vancouver, Washington 98684

Re: 2005P-0121  
Reclassification Petition for the Non-invasive Bone Growth Stimulators

Dear Mr. Carroll:

The Food and Drug Administration (FDA) acknowledges your request to place Docket# 2005P-0121/CCP 1 on hold pending receipt of a petition amendment. The FDA has reviewed the above referenced petition for reclassification pursuant to section 513(e) of the Food Drug and Cosmetic Act. While we have determined that your petition includes all of the essential components as described within 21 CFR § 860.123 and could go to panel, the FDA believes that the following concerns, (informally submitted for your review on July 27, 2005), should be considered:

1. In support of this petition, the sponsor has provided “new information”, as described within § 513(e) - “publicly available, valid scientific evidence”, which includes the following (42 Literature articles listed within Appendix A):
  - a. sham-controlled, double-blinded, prospective studies,
  - b. standard-of-care controlled (non-sham), prospective studies,
  - c. historic-controlled, retrospective studies,
  - d. and non-controlled studies.

These articles appear to differ considerably in respect to study size, drop-out rates, clinical/imaging evaluation, prior treatment, site of treatment, and concurrent treatment. etc. The petition does not appear to include an analysis of these disparate study parameters and their affect on the validity of the scientific evidence. The petition should be revised to include rationale for consolidating the providing literature studies as scientific evidence considering the studies inconsistencies. In addition, the petition does not appear to include literature articles which may be unfavorable to the petition. Additional research may be necessary to verify that the submitted summary literature is an adequate sample of the available scientific evidence and includes scientific evidence which may not support this petition.

2005P-0121

LET 3

2. The petition appears to suggest that subsequent to the reclassification of non-invasive bone growth stimulators your proposed device would be “exempt from 510(k) requirements” (pg 89-90) (i.e. not require a 510(k) marketing submission). This is not acceptable. You do not currently own a legally marketed bone growth stimulator PMA device or a Pre-amendment device. Therefore, the submitted petition is considered to be a citizen’s petition for the reclassification of the product group and NOT your proposed device. If the reclassification is granted, RS Medical must submit a 510(k) and receive a substantially equivalent determination prior to marketing your device.
3. The 33 literature articles submitted to support the indication for use, “Treatment of established non-unions acquired secondary to trauma,” includes 5 Capacitive Coupling (CC) and 28 Pulsed Electromagnetic Field (PEMF) studies. The petition does not appear to include valid scientific evidence to support the use of Combined Magnetic Field (CMF) devices for the treatment of established non-unions. Additional scientific evidence should be provided to support the use of CMF devices for this indication for use.
4. The petition’s risk analysis identified four general categories of health risk to the patient; electric shock, burn, skin irritation/allergic reaction, and inconsistent or ineffective treatment. The petition’s risk analysis does not appear to adequately assess the risk of harm to the patient from the presence of metallic and/or electrical implants (including cardiac pacemakers, neurostimulators, and internal/external fixation). In addition, the petition’s risk analysis does not appear to address risk associated with electrical stimulation at the biologic level, including carcinogenicity, mutagenicity, cell toxicity, and teratological effects. The risk analysis should be revised to include these risks.
5. The petition has identified thermal burns as a potential risk associated with this device. The petition has also recognized that the majority of burn-related, adverse events occur while the patient is using and recharging the device during sleep. To mitigate this risk the petition proposes appropriate warning labeling. Considering that treatment may be prescribed for up to 14 hrs per day, this mitigation may not be reasonable as a patient may not have the time to adequately charge and use the device during their wakeful hours. The petition should be reevaluated to provide further mitigating activities to minimize the risk of thermal burns to the patient.
6. The proposed special controls appear to outline a general set of output waveforms (burst length, pulse amplitude, pulse amplitude, and frequency) upon which substantial equivalence might be established. However, it is unclear if these parameters are adequate, in themselves, to assure safety and effectiveness. These device waveform parameters do not appear to provide a complete set of technical parameters which would be sufficient to assure the reproducibility of clinically effective treatment. The parameters do not address the distribution of the induced magnetic/electric fields, coil geometry, effective dosimetry of the resulting electrical gradient/magnetic field

(magnetic field mapping), material and dimensions of the electrodes (capacitive plates), pulse rise/fall time, pulse width/shape, symmetry/asymmetry of waveform, and other technical parameters. In addition, the petition should include rationale to justify how the proposed technical specifications are sufficient to validate an effective clinical treatment signal. The petition should be revised to address what range of technical specification is necessary to ensure a clinically effective treatment signal/dose.

As you have requested, the petition will not be presented at the Orthopedic and Rehabilitation Devices Panel meeting tentatively scheduled for September 8-9, 2005. As a result of your request, the FDA has placed the reclassification petition on hold. The FDA will continue the review of your petition upon receipt of additional information addressing these concerns. In anticipation of presenting the above referenced petition to an expert panel, sufficient time (2 months) should be provided for FDA review prior to a desired panel meeting date. Any additional information should reference the above docket number (2005P-0121/CCP 1) and be submitted to:

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

If you have any questions related to reclassification, please contact Ms. Marjorie Shulman at (301) 594-1190, ext. 132. For scientific and technical assistance, please contact Mr. Michel Janda by phone at (301) 594-1307, ext. 137.

Sincerely yours,



Donna-Bea Tillman, Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health