



CRYOVASCULAR
systems, inc.

September 9, 2002

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Dockets Management Branch (HFA-304)
Food and Drug Administration
5630 Fischers Lane
Room 1061
Rockville, Maryland 20852

RE: FDA Docket No. 02D-0228; Comments on *Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA* (draft dated June 12, 2002)

Dear Sir or Madam:

The comments detailed below are specific to the *Implantable Middle Ear Hearing Device; Draft Guidance for Industry and FDA* released for comment on June 12, 2002.

1. On page 5, under the heading **Pre-implant testing**, it is suggested that the first two sentences be modified to read:

Design verification and validation activities should be conducted so that there is assurance that components meet established requirements. The evaluations should ensure that the external and internal implant system, as well as any accessories, operate within defined specifications on an assembly level and on an overall system level.

2. On page 7, under the heading **Electromagnetic Compatibility (EMC) Testing**, it is suggested that the first sentence be eliminated since the sources of electromagnetic interference are covered in the standards referenced in paragraph 2. It is suggested that the opportunity for a sponsor to declare conformance(s) to the applicable EMC standards be specifically authorized in this section of the guidance document.

3. On page 13, under the heading **Post-implant testing**, it is suggested that the last two sentences of paragraph 2 and the entirety of paragraphs 3 and 4 be moved to page 5 under the heading **System Output and Response**. This suggestion is based upon the fact that characterization of device performance with human temporal bones should be conducted early in the design phase and prior to clinical investigation in human subjects.

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4. On page 18, under the heading Package Labels, bullet number seven should be corrected to read:

The label of the device packaging must bear the prescription device statement in accordance with 21 CFR 801.109(b)(1), "CAUTION: Federal law restricts this device to sale by or on the order of a physician."

These comments do not represent the opinion(s) of any company, trade association, nor are they specific to the role of the undersigned as Industry Representative to the FDA Ear, Nose and Throat Devices Panel. If I can provide any information or clarification related to these comments, please do not hesitate to telephone me at (408) 866-3204.

Sincerely,



R. Michael Crompton
Vice President, Regulatory / Clinical Affairs
and Quality Assurance