



November 9, 2001

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

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Re: Docket No. 01D-0311

Dear Sir or Madam:

E. Benson Hood Laboratories, Inc. ["Hood Laboratories"] strongly supports FDA's "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA" ["Guidance"] which was published on August 15, 2001. Hood Laboratories submitted a reclassification petition to FDA because we believed that special and general controls could provide a reasonable assurance of the endolymphatic shunt tube with valve's safety and effectiveness. We appreciate FDA's thorough review of our reclassification petition and the time and energy the agency devoted to its comprehensive Guidance.

Under the Federal Food, Drug, and Cosmetic Act ["Act"] special controls are any controls, other than the Act's general controls, that can reasonably assure a class II device's safety and effectiveness. The Guidance will serve as the endolymphatic shunt tube with valve's special control when the device is reclassified as a class II device. See 66 Fed. Reg. 42,870 (Aug. 15, 2001). The endolymphatic shunt tube with valve is a perfect device to be regulated by a special control because parameters can be set for the device's design, manufacture, and labeling that will assure its safety and effectiveness. The device has been marketed for over 20 years for use in a fairly small population. Thus, information about its proper use and risks has been available for years and the physicians who rely on the device are highly knowledgeable about it.

A manufacturer will use FDA's Guidance when submitting a pre-market notification, or 510(k), for an endolymphatic shunt tube with valve. The Guidance suggests measures to be followed that will address risks associated with the device. The agency identified two risks to health associated with the device: "(1) a build up of fluid pressure in the inner ear due to a clogged or inoperative valve; and, (2) revision surgery to correct a defective valve, including infection." FDA identified five special controls to address the device's potential health risk: labeling, valve performance, materials specification, biocompatibility testing, and sterility testing.

Labeling

FDA states the indication for use should include the following statement: "The device is intended for use in patients who have been diagnosed with Meniere's disease and for whom more conservative methods of treatment, including medical treatment and less complex surgical procedures such as sac surgery without shunt, may not be

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considered appropriate by the attending physician.” The agency also believes that the labeling should include a statement which explains that scientific data have not established that the device operates as a one-way valve in vivo to maintain normal endolymphatic pressure, but that observational data, including case reports, suggest the shunt may preserve hearing and reduce or eliminate symptoms of Meniere’s disease in some patients who require surgical intervention.

Hood Laboratories fully supports these labeling statements because they are accurate and they tell doctors and patients the information they need to know. The indication for use statement defines the patient population in which the benefits from using the device will outweigh the risks. These are patients facing only the option of destructive surgery which dissects the nerve and renders the patients deaf. Additionally, the labeling accurately describes the scientific data on the device. Physicians need to know that this device may preserve hearing and reduce or eliminate symptoms of Meniere’s disease. Indeed, doctors who have used the device have endorsed it and provided case reports of the device’s benefits.

Valve Performance

In this special control, FDA again recognized the importance of physicians’ experience with the Hood Laboratories’ endolymphatic shunt tube with valve. Because this observational data (referenced above) existed for the Hood Laboratories’ device, FDA used the device as a benchmark. Thus the agency concluded valve performance data would be needed to demonstrate equivalency to the currently marketed device. Specifically, a manufacturer is required to conduct 100 percent sample testing prior to implantation to ensure that the valve opening pressure specification (4.3 to 6.0 inches of water) is met.

Hood Laboratories endorses this requirement because it recognizes doctors’ positive experience with the valved shunt tube. FDA relied on published data and physicians’ experience to determine that Hood Laboratories’ device is an appropriate benchmark. Because the Hood Laboratories’ device has been used safely for years, this clinical test is derived from this experience and will identify nonfunctioning valves.

Materials Specification

FDA’s Guidance requires future valve shunts to have similar dimensional, flexibility, strength, and durability characteristics as the currently marketed device. Where biocompatible material is used that is not identical to that of the Hood device, the new device should have the same tensile strength, durometer, elongation, and hardness characteristics. Where materials are not identical, additional performance or clinical data may be necessary.

Hood Laboratories agrees that these requirements are appropriate for future devices. Hood’s specifications are based on a silicone product which has reasonably predictable characteristics. Silicone and other materials used by Hood allow the device to

have the right amount of flexibility that is needed in order to bend it within the mastoid cavity. Similarly, these materials are not too floppy and do not allow the device to kink or lose its shape and structure. To the extent other materials are used in valve shunts, the agency's requirement of performance or clinical data is reasonable.

Similarly, Hood Laboratories advocates that a new device share the same strength characteristics as Hood's device. Hood employs a lateral force test to ensure body integrity of the device. Body integrity is the strength of the connection of the tubing to the valve body. Comparing new devices to Hood's device for this characteristic is a good idea because a device normally implanted into a patient would never experience the amount of force generated in Hood's test. Therefore, testing a device relative to Hood's device will guarantee that the new device will not fall apart under expected conditions of use.

Finally, the Hood Laboratories device's specifications for Inside and Outside Diameters have been proved to be satisfactory and provide an appropriate model. These specifications must be accurate because otherwise the tube will not fit into the duct and endolymphatic fluid will not freely flow through the tube. Similarly the body of the shunt must be correctly sized because if it is too large, it will not fit in the mastoid cavity and if it is too small, the slit valve will not fit into the shunt body. Thus, Hood Laboratories agrees that the new devices must have similar dimensional specifications to the Hood device.

Biocompatibility Testing

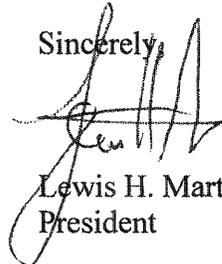
The Guidance requires manufacturers of the endolymphatic shunt tube with valve to follow the biocompatibility testing procedures listed in ODE's Blue Book Memorandum G95-1, "Use of International Standard ISO-10993-1."

Sterility Testing

FDA's Guidance requires manufacturers to adhere to the agency's "510(k) Sterility Review Guidance" (K90-1) in order to control the risk of infection. Hood Laboratories maintains that the device be processed via steam sterilization to an SAL of at least 10^{-6} which is an acceptable level of sterilization according to the 510(k) Sterility Review Guidance.

In conclusion, Hood Laboratories supports the agency's Guidance and believes that following the special controls outlined in the Guidance will provide a reasonable assurance of safety and effectiveness for the endolymphatic shunt tube with valve.

Sincerely,



Lewis H. Marten
President

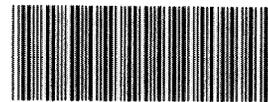
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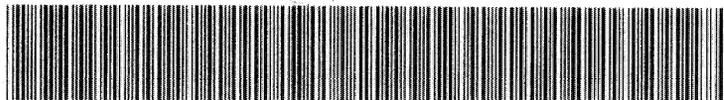


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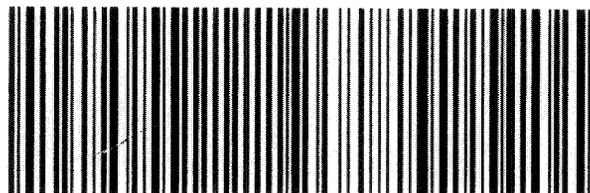
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