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November 9, 2001

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

Re: Docket No. 97P-0210

Dear Sir or Madam:

E. Benson Hood Laboratories, Inc. ["Hood Laboratories"] supports FDA's proposed reclassification of the endolymphatic shunt tube with valve from class III to class II. The "device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease." Proposed Rule, Ear, Nose, and Throat Devices; Reclassification of Endolymphatic Shunt Tube with Valve, 66 Fed. Reg. 42,809, 42,810 (Aug. 15, 2001).

Hood Laboratories manufactures the only endolymphatic shunt tube with valve that is legally marketed in the United States for the above intended use. The device is used in a small sub-population of Meniere's patients when other treatments prove ineffective. Only a small group of physicians relies on this device for a distinct type of case. Indeed, implanting an endolymphatic shut tube is a physician's last option in treating a Meniere's patient; without the shunt tubing the next step in treatment is transaction of the nerve which in all cases results in deafness. The labeling of the device reflects the limited conditions under which the device can be used.

Because the endolymphatic shunt tube with valve is used in such a small population and is marketed by only one manufacturer, the failure to reclassify the device would result in the product being withdrawn from the market. Hood Laboratories could not justify undertaking a PMA when the product has such a limited distribution; less than one hundred of these devices are sold each year. Needless to say, withdrawing the product would severely affect those patients for whom the device is intended, because their only remaining treatment option is guaranteed to result in deafness. Indeed, the product's withdrawal would be an even worse outcome in light of the device's proven safety record. FDA noted in its proposed reclassification that both the valved and nonvalved endolymphatic "shunts have been used for more than 20 years without reportable events of major or frequent safety or effectiveness problems." 66 Fed. Reg. at 42,811. Physicians familiar with the endolymphatic shunt tube with valve have strongly endorsed the device. Hood Laboratories submitted to FDA letters from physicians who summarized their positive experience with the device. As one physician states, "Overall, I feel that the risk benefit assessment is quite reasonable and favorable for this non-destructive surgical intervention for patients with Meniere's disease and endolymphatic hydrops refractory to medical treatment." Letter from Dr. I. Kaufman Arenberg to Lewis Marten, President of Hood Laboratories (April 1, 1991).

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Reclassifying the endolymphatic shunt tube with valve makes sense from both a public health perspective and a legal perspective. When FDA determines the safety and effectiveness of a device for purposes of classification, that determination is a context specific undertaking. The following factors, among others, must be considered: the person for whom the device is intended, the conditions of use, the device's probable benefit to health weighed against any probable injury or illness, and device's reliability. 21 C.F.R. § 860.7(b). Because the endolymphatic shunt tube with valve is intended for such a small population in such limited conditions, because its benefits certainly outweigh the alternative, namely deafness, and because it has a proven track record, a lower classification than class III is appropriate. The device does not fall within the definition of a class III device: it does not support or sustain human life, it is not of substantial importance in preventing impairment of human health, and it does not present a potential unreasonable risk of illness or injury. *See* § 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act ["Act"]. Even if it did fall within the definition of a class III device, there are general controls and special controls, which would provide reasonable assurance of the device's safety and effectiveness. *See* § 513(a)(1)(B) of the "Act" (defining a class II device).

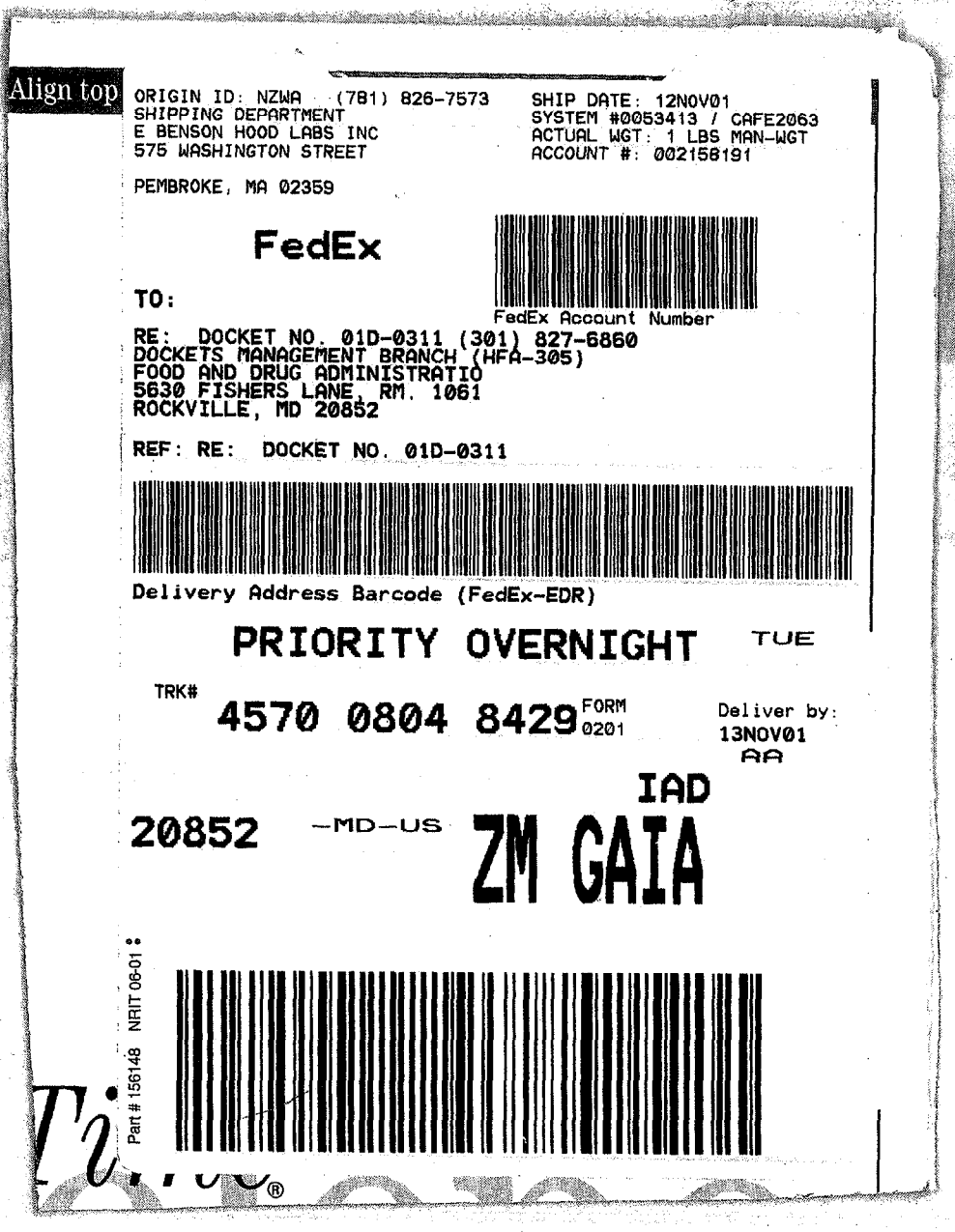
The failure to reclassify the endolymphatic shunt tube with valve also would raise a question of fundamental fairness because like devices should be subjected to similar regulatory requirement. FDA found that new information provided by Hood Laboratories in its second reclassification petition demonstrated that risks, such as infection from revision surgery and clogging, had similar occurrences in both the valved and nonvalved endolymphatic shunts. 66 Fed. Reg. at 42,810. Hood Laboratories pointed out that "infection is not a reason to distinguish between the two types of shunts through differing classifications" because the solution to infection is proper sterile procedure during the revision surgery, a solution which is unrelated to the devise and which would not be addressed in a PMA. Additionally, FDA noted that data existed which suggest improved hearing in patients with the valved shunt as compared to patients who have the nonvalved shunt. 66 Fed. Reg. at 42.811 (citing references 8 and 9 in the preamble to the proposed reclassification). Because the nonvalved endolymphatic shunt is a class II device, see 21 C.F.R. § 874.3820, treating the vavled shunt differently would make little sense from a public health perspective and, in fact, would result in the type of inequity that the classification scheme is designed to avoid. The available data demonstrate that the valved and nonvalved shunts are indistinguishable in terms of safety and effectiveness.

Hood Laboratories appreciates FDA's careful review of its reclassification petition and strongly supports the agency's proposed rule.

Sincerely,

Lewis H. Marten
President

LHM/slh



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