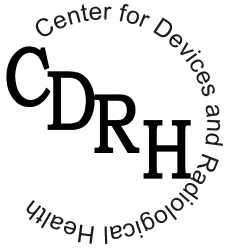
Guidance for Industry

# Noise Claims in Hearing Aid Labeling

**Document issued on: October 21, 1998**




**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Ear, Nose and Throat Devices Branch**
**Division of Reproductive, Abdominal, Ear,**
**Nose and Throat and Radiological Devices**
**Office of Device Evaluation**

# Preface

## Public Comment:

Comments and suggestions may be submitted at any time at any time for Agency considerations to Harry Sauberman, P.E., CDRH, 9200 Corporate Blvd, HFZ-470, Rockville, MD 20850 or by e-mail to hrs@cdrh.fda.gov. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, also contact Mr. Sauberman at (301) 594-2080.

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# Noise Claims In Hearing Aid Labeling

Manufacturers who make noise claims in their labeling for hearing aids (e.g. improved speech understanding in noisy environments) are no longer required to submit a 510(k) premarket notification to obtain a “substantially equivalent” decision in support of these claims.

Under the Food and Drug Administration Modernization Act (FDAMA) of 1997, air conduction hearing aids are exempt from premarket notification subject to limitations of exemptions found in 21CFR 874.9.

The limitations of exemptions basically state that a major change in the intended use of a hearing aid or a change in the fundamental scientific technology would require a new 510(k) submission. Specifically, a change that only involves the addition of a noise claim to the labeling, including promotion and advertising materials, does not exceed the limitations of exemptions and does not require a new 510(k).

Manufacturers should develop substantiating data, from scientific and/or clinical studies, to support their claims. This data should be kept and maintained at the manufacturer’s facility. The data should be made available for review at the request of the FDA or made available during an FDA inspection. Claims that are determined to be unsubstantiated may result in the device being misbranded under Section 502 of the Federal Food, Drug and Cosmetic Act.