

K 013298/A?

audible innovations.



June 19, 2002

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Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

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"Request for Evaluation of Automatic Class III Designation" under 513(f)(2)

Re: K013298 Trade Name: RetroX

To Whom It May Concern:

The letter dated May 24, 2002, informed me of the not substantially equivalent determination and the Class III designation for the RetroX. Furthermore, the letter stated that the RetroX may be a candidate for Evaluation of Automatic Class III designation.

I request that the RetroX be evaluated for consideration as a Class II device with special controls in addition to general controls applicable to conventional Class I air conduction hearing aids. Clinical experience, audiological information, and supporting documentation previously submitted with 510(k) #K013298 supports this request.

The successful clinical experience of the RetroX to date has been dependent upon the skills and teamwork of Trained Ear Surgeons and competent dispensers of conventional hearing aids. Proper medical and audiological screening, effective education and counseling of prospective wearers, and proper fitting of the RetroX tube have proven to be important aspects relative to safety and effectiveness.

The attached 5-page document includes a complete discussion of the proposed controls and a discussion of the potential benefits of the device when compared to the potential or anticipated risks when the device is used as intended. The last page is an addendum summary of the proposed controls to facilitate review and processing.

Please call me with any questions. I can be reached at 781-632-8742.

Sincerely,

David J. Navaroli, Jr., President  
auric hearing systems, inc.

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