DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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NOV 2 6 2008

William J. Kennick, Esq.
1755 York Avenue
New York, NY 10128

Re: Citizen Petition FDA-2008-P-0197
Dated March 14, 2008
Filed March 26, 2008

Dear Mr. Kennick:

This letter responds to the above referenced citizen petition (the Petition) filed on March 26, 2008 with the Food and Drug Administration (FDA, the agency). In the Petition you request that the Commissioner of Food and Drugs determine whether the Tomatis Electronic Ear is a medical device, and "then refrain from taking any form of administrative action, or to approve the device" (emphasis in the original). For the reasons discussed below, based on the information provided in the Petition, we have determined that the Tomatis Electronic Ear is a medical device and, accordingly, we deny your request to refrain from appropriate administrative action.

Background

The Federal Food, Drug, and Cosmetic Act (the FFDCA or the act) states, in relevant part:

The term "device" [ ] means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Section 201(h) of the act, 21 USC 321(h).

As described in the Petition, the Tomatis Electronic Ear is used to administer "scratch, filtered music" to a person through specific earphones that include a "bone conduction device . . . to vibrate against the patient's skull" (Petition at ¶ G). In addition, the Petition states that the "altered sound should not be disregarded as a harmless [ ] device" because it "has an impact on

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[the user's] balance," and further, that the device should be taken "seriously, and its use encouraged as "[n]o other treatment for autism works nearly as well." (Petition at ¶ H.) The Petition states that the Tomatis Electronic Ear has been used to "treat[ ] upwards of 2000 autistic children," and has "improved the condition of" those treated (Petition at ¶ E).

Tomatis Electronic Ear is a Medical Device

On the basis of the product description that the Petition provides, the agency concludes that the Tomatis Electronic Ear meets the definition of a medical device. Rather than an "educational device" (¶ F), the product is intended to treat autism, a medical condition, and is intended to affect a patient's balance function, by "treating the ear with sound [to] alter the balance or vestibular function of the ear" (¶ H). The product is subject, therefore, to applicable medical device laws and regulations.

Medical Device Approval

As an alternative to declaring that the Tomatis Electronic Ear is not a medical device, the Petition requests that Commissioner of Food and Drugs approve the device (Petition at ¶ B). Within the FDA, the Center for Devices and Radiological Health (CDRH, the Center) is responsible for the review, evaluation, and clearance/approval of medical devices such as the Tomatis Electronic Ear. Section 513 of the act (21 U.S.C. 360c) provides for three device categories or classifications: class I (general controls); class II (special controls); and class III (premarket approval). The classification of a device is determined by the regulatory controls necessary to provide reasonable assurance of its safety and effectiveness. Device classification is also determined by the intended use, as well as indications for use, of the device, which must be included in the device's labeling. (See 21 CFR parts 801 and 860.)

FDA will clear or approve a product after reviewing a submission from the applicant and determining that the applicable requirements under the FFDCA have been met. Examples of such a submission include a premarket notification (see 21 CFR 807.87) or a premarket approval application (see 21 CFR 814.20). However, you have not made such a submission for this product; without a premarket submission FDA cannot determine whether your product meets the applicable premarket requirements. Accordingly, FDA cannot clear or approve the medical device. We recommend that the manufacturer of the Tomatis Electronic Ear device contact CDRH's Office of Device Evaluation to determine the information needed to support a submission seeking clearance or approval of the device. For consumer questions or manufacturer's assistance, please contact CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by e-mail at dsmica@cdrh.fda.gov, or by telephone at 240-276-3150 or 800-638-2041.

Finally, we note that the Petition states that the electronically modified sounds produced by the Tomatis Electronic Ear could be created using various software applications and then made available on a CD or via the Internet (the Petition at ¶ J). The Petition goes on to say that the resulting product "could presumably be banned as dangerous except that this violates the free speech clause [of the Constitution]" (*id.*). While the agency is not precisely clear what is meant by this statement, medical devices automated by computer software may still meet the definition of, and be regulated as, medical devices.

Conclusion

Tomatis Electronic Ear is a medical device subject to laws and regulations applicable to medical devices. You have not submitted a premarket notification or a premarket approval application for this device, and accordingly FDA has not cleared or approved the product. For these reasons your petition is denied.

Sincerely,

Jeffrey Shuren
Associate Commissioner for
Policy and Planning

Enclosures (2):

21 CFR 807.87
21 CFR 814.20