

May 16, 2005

TO:

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Division of Dockets Management,

Food and Drug Administration,

Department of Health and Human Services,

5630 Fishers Lane, rm. 1061, Rockville,

MD 20852. USA

Citizen Petition

The undersigned submits this petition under statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to change the regulation effecting EEG electrodes, currently classified as class II and requiring 510K approvals.

A. Action requested

Change the classification of EEG electrodes, currently calcified as class II under 882.1320 to class 1, exempt from 510K.

B. Statement of grounds

An EEG electrode is simply a small piece of metal, usually made of Silver, but often from Tin plate about 3/8" in diameter, which is bare, or silver or gold plated, to which a wire and a connector are attached. The electrode's purpose is to transfer very small electrical signals from the skin of the head to the recording EEG machine.

The electrode is completely passive, meaning that is does not amplify, filter or change the signal in any way. It poses no risks of any kind, and its performance is very easily monitored by the technician, who can choose to use higher quality or lower cost electrodes for his application. EEG recording is not life supporting. There is also no issue of depolarization as is the case with ECG electrodes.

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The difference between good electrodes and bad electrodes is in the amount of noise they generate, which is clearly visible to the technician performing the study, They also

differ in their construction, meaning that good quality electrodes will last linger in use.

The electrode is a negligible part of the EEG system. There are voluntary standards for skin contact electrodes by the AAMI, but these apply to ECG electrodes, not to EEG.

C. Environmental impact

There are no Environmental issues of any kind relating to EEG electrodes.

D. Economic impact

Eliminating the need to approve EEG electrodes by 510K will lower the regulatory burden or electrodes manufacturers, which will allow them to lower the cost of these products on the market, and allow more people to purchase higher quality products.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Noan Hada (Signature)

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Beceived 5/31/2005

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