S.L.P LTD.

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513 (e) Petition

TO:

Food and Drug Administration,
Center for Devices and Radiological Health,
Regulations Staff (HFZ-215),
1350 Piccard Dr.,
Rockville, MD 20857;
USA

By

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2005P.0213

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S.L.P LTD. Scientific Laboratory Products

MEDICAL DESIGN EXCELLENCE AWARDS

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(1) A specification of the type of device for which reclassification is requested;

The device for which reclassification is requested is simple EEG electrodes, in the form of a metallic electrode connected to a wire terminated in a connector, and used to record EEG signals in neurological procedures. This petition relates only to gel-less electrodes, which are applied with conductive gel or paste.

(2) A statement of the action requested by the petitioner, e.g., "It is requested that _ device(s) be reclassified from class III to a class II";

It is requested that the FDA Changes the classification of EEG electrodes, currently calcified as class II under 882.1320 be reclassified as class 1, exempt from 510K.

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

An EEG electrode is simply a small piece of metal, usually made of Silver, but often from Tin plate, sintered silver/silver-chloride or gold-plated silver about 3/8" in diameter, to which an electrical 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 depending on his needs and application. EEG recording is not life supporting. There is also no issue of depolarization as is the case with ECG electrodes. The electrodes are made from metals, with skin contact provided by application of a suitable, FDA approved gel or paste that insures bio-compatibility and electrical contact.

The difference between good electrodes and lower quality 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 longer in use.

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

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

Looking at just the EEG electrode, when connected to an FDA-approved EEG monitor or recorder:

1. Is the device life-sustaining or life-supporting?

   Answer: **No.** All regulatory burden is on the recorder or monitor. The electrode plays a negligible part in the monitoring process.

2. Is the device for a use which is of substantial importance in preventing impairment of human health?

   Answer: **No.** All regulatory burden is on the recorder or monitor. The electrode plays a negligible part in the monitoring process.

3. Does the device present a potential unreasonable risk of illness or injury?
   Answer: **No.**

4. Did you answer "yes" to any of the above 3 questions?

   Answer: **No**

5. Is there sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness?

   Answer: **Yes**

The electrodes should, therefore, be classified as class 1.

(5) A statement of the basis for disagreement with the present classification status of the device;

The miss-classification results for the non-distinction between the machine – the EEG recorder or monitor, which is a complex electronic system, and the EEG electrode, which is only a small accessory used together with the machine. The performance of the recorder is dependent to some extent on the performance of the electrodes, but their effect is easily discernible from the recording, and the user may select electrodes to provide the level of performance needed. In fact, in 510K applications of EEG recorders, there is usually no reference to the type or performance of the electrodes which must be used with the recorder – indicating

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that they are a non-critical part of the recording system. There are no significant safety issues relating to the electrode itself, except the connector type and bio-compatibility, which can be covered by the specific requirement that DIN safety connectors are used, and that FDA approved paste to gel be used.

(6) A full statement of the reasons, together with supporting data satisfying the requirements of 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

Eliminating the need to approve such EEG electrodes by 510K will lower the regulatory burden on 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. All safety requirements are already handled by the system, and the electrode, as a totally passive element, have negligible effect on total safety.

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

Non known.

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

No new information.

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

No new information.

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

SLP is a manufacturer of EEG electrodes of different types, and is interested in marketing these electrodes in the USA without a need to submit a 510K request. These electrodes are already marketed world-wide except the USA. Many manufacturers also manufacture similar electrodes.

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