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510(k) SUMMARY
Aspect Medical Systems, Inc. Zipprep EEG Sensor

Company Name

Aspect Medical Systems, Inc.
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Device Name/Classification

Proprietary Name: Aspect Medical Systems Zipprep EEG Sensor
Common Name: Electrode, Cutaneous Electrode

Cutaneous Electrodes have been classified by the Neurological Devices Panel as Class II devices. Refer to 21 CFR 882.1320.

Description

The Aspect Medical Systems, Inc. Zipprep™ Disposable EEG Sensor (hereafter referred to as the Aspect EEG Sensor, is a rectangular shaped, pre-gelled array of three (3) Zipprep electrodes that is applied to the patient's skin to record electro-physiological (such as EEG) signals.

It is a low impedance, single patient use, disposable electrode sensor that is designed for application to the frontal/temporal area. The main body of the Aspect EEG Sensor, which houses two (2) electrodes, is placed on the forehead. The satellite, which houses one (1) electrode, is placed over the temple area.

Electrode Area of Sensor

The Zipprep electrode area of the Sensor is composed of a basepad with a pressure sensitive adhesive that contacts the skin. A pocket in the basepad houses the flexible tines disk, which adheres to a ring shaped piece of film. A polyurethane sponge is placed over the tines. The aqueous gel (hydrogel) is also placed in this area.

The Zipprep electrode is "self-prepping", in that no brisk skin or alcohol rub is necessary to prepare the skin to lower the impedance prior to applying the electrode. The flexible tines in the Zipprep electrodes part the outermost layer of skin while the gel flows around the tines and forms a conductive bridge with the skin.

Sensor

Two (2) Zipprep electrodes are mounted in a rectangular shaped basepad composed of polyethylene (PE) foam. The third Zipprep electrode (the satellite electrode) is mounted in a smaller, rectangular shaped basepad also composed of PE foam. On one side of the foam (the skin side) there is a pressure sensitive adhesive, which allows it to adhere to the skin with no additional taping necessary. On the other side of the PE foam there is a Mylar substrate. The electrode sections are connected by a thin strip of Mylar. Flexible circuit technology is utilized by printed silver/silver chloride ink on the Mylar substrate. A polyester insulator is used to restrict electrical contact to the element area.

The Aspect EEG Sensor has a flexible tab on one end, with a polypropylene housing designed to provide rigidity to the flexible tab.

Indications for Use

The Aspect EEG Sensor is applied directly to the patient's skin to enable recording of electro-physiological (such as EEG) signals.

Statement of Substantial Equivalence

The Aspect EEG Sensor is substantially equivalent to the following devices:

1) Aspect Medical Systems Zipprep™ Electrode, 510(k) #K940802

2) NDM ECG Backpad, 510(k) #K761301

Similarities

1) The Aspect EEG Sensor is similar to the 510(k) Aspect Zipprep Electrode in the following ways:

   - o The indications for use are identical.
   - o The technology is identical
   - o Both use silver-silver chloride as the conducting material. In addition, the following materials are the same:
     - Identical polyethylene basepad material
     - Identical nylon flexible tines
     - Identical liquid gel - hydrogel
     - Identical silver-silver chloride conducting material

   The Aspect EEG Sensor is similar to the NDM ECG Backpad in the following ways:

- o Fixed array of electrodes
- o Pre-gelled
- o Flexible circuit technology

Differences

1) The Aspect EEG Sensor is different from the 510(k) Aspect Zipprep Electrode in the following minor ways:

   - o The Aspect EEG Sensor has a polyurethane sponge over tines, whereas the Zipprep Electrode does not.
   - o The Aspect EEG Sensor has flexible Mylar circuitry with Ag/Ag Cl conductors and a flexible tab for connection. The Zipprep Electrode has standard snap construction.
   - o The Aspect EEG Sensor has no foam ring.
   - o The Aspect EEG Sensor has a film ring located beneath the tines
   - o The Aspect EEG Sensor adhesive is slightly more adherent than the adhesive used on the Zipprep Electrode.

2) The Aspect EEG Sensor is different from the NDM ECG Backpad in the following minor ways:

   - o The Aspect EEG Sensor has 3 electrodes. The NDM Backpad has 4.
   - o The Aspect Sensor is used for EEG recordings and is placed on the forehead, whereas the NDM Backpad is used for ECG recordings and is placed on the back.
   - o The Aspect EEG Sensor is approximately 8.5" x 1.5". The NDM Backpad is approximately 9" x 7".
   - o The Aspect EEG Sensor has Silver-silver chloride printed circuitry. The NDM Backpad has Copper printed circuitry.

Testing

1) Biocompatibility testing was conducted in accordance with the International Standard ISO-10993, Biological Evaluation of Medical Devices Part I: Evaluation and Testing. Results are summarized as follows:

Primary Skin Irritation - Pass; not a primary skin irritant
Cytotoxicity - Pass; results indicate the device passes relative to its intended use
Delayed Contact Sensitization study - Results due May 31, 1996

2) Electrical testing was conducted in accordance with the American National Standard for Disposable ECG Electrodes, developed by AAMI and approved in December, 1991 by ANSI. The Sensor passed all testing in accordance with the Standard.

3) A clinical evaluation was conducted at Ohio State University. Impedance, signal quality, usability and skin irritation were evaluated. Results indicate the Aspect EEG Sensor performs in the manner in which it is intended.

5/8/96