K960732

HYDROSPOTS
SUMMARY OF SAFETY AND EFFECTIVENESS

Date:	February 20, 1996
Company:	Physiometrix, Inc. Five Billerica Park 101 Billerica Avenue N. Billerica, MA 01862
Contact:	Dawn E. Frazer Director, Regulatory Affairs & Quality Assurance (508) 670-2422 (800) 474-9746
Subject Device:	Model 1501, HydroSpot EEG Electrodes Model 1500, HydroSpot EEG Leadwires
Predicate Device:	K930080, HydroDot NeuroMonitoring System
Classification:	Class II, CFR 21 Part 882.1320, Cutaneous Electrodes
Description:	The HydroSpots are single-use, pre-gelled, disposable, silver/silver chloride EEG electrodes. They are designed to satisfy the customers who prefer the traditional electrode placement system that involves measuring the head, marking the electrode locations, and adhering electrodes to the head. The HydroSpots have a similar form factor to the industry standard leadwire attached electrodes. The product design mimics the traditional electrode placement system while maintaining the other benefits provided by the headpiece electrodes that are listed below. a. Ease of patient clean up. Both electrodes use a conductive adhesive gel to transmit the signal from the body's surface to the silver/silver chloride substrate. The hydrogel minimizes patient clean up as the hydrogel removes cleanly from the hair. b. Ease of electrode clean up. The traditional electrodes have to be washed between patients while the HydroSpots and HydroDot electrodes are disposable.
Intended Use:	The HydroSpots are intended as direct substitutes for existing reusable EEG electrodes.
Design/Materials:	The HydroSpots are fabricated from a combination of materials that are widely used in the sensing electrode industry, silver/silver chloride, conductive hydrogel, and skin contact adhesive.

The design features a pre-gelled cup electrode with an optional adhesive ring that may be exposed and used to secure the electrode to the skin. The electrode is designed to mate with a wire such that the wire is reusable and the electrode which makes direct patient contact is disposable.

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