

K970094

Physiometrix, Inc.
510(k), Premarket Notification
Model 1700, HydroPrep

MAY 14 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

Date: February 24, 1997

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact: Dawn E. Frazer
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Subject Device: Model 1700, HydroPrep

Predicate Device: K885306, NuPrep (Weaver & Co.)

Classification: 882.1275 Electroconductive media

Description: HydroPrep is a skin preparation solution similar to NuPrep. It is different in that is has more water and more salt than the current formulation. It used the same preservatives and gritty media.

Intended Use: HydroPrep and NuPrep are skin preparation materials that are designed for use by EEG Technicians. Both substances are applied to the skin surface with a cotton swab in order to reduce skin impedance and increase signal quality recorded with EEG electrodes. HydroPrep is not intended for use with stimulating electrodes.