Recognized Consensus Standards

Recognition List Number: 038 FR Publication Date: 01/27/2015

Part B: Supplementary Information


Date of Standard: 2012.

Address of Standards Development Organization:
Institute of Electrical and Electronic Engineers (IEEE)
345 East 47th Street
New York, NY 10017

CDRH Offices and Divisions associated with recognized standards:
(1) OFFICE OF DEVICE EVALUATION (ODE)
   DIVISION OF NEUROLOGICAL AND PHYSICAL MEDICINE DEVICES (DNPMD)
(2) OFFICE OF COMPLIANCE (OC)
   DIVISION OF ENFORCEMENT B (DOEB)
(3) OFFICE OF SCIENCE AND ENGINEERING LABORATORIES (OSEL)
   DIVISION OF BIOMEDICAL PHYSICS (DBP)
(4) OFFICE OF SURVEILLANCE AND BIOMETRICS (OSB)
   DIVISION OF POSTMARKET SURVEILLANCE (DPS)
   POSTMARKET EVALUATION BRANCH II (PEBII)

Devices Affected:
Biofeedback devices that use electroencephalograph (EEG) (for any intended use or IFU) and cutaneous electrodes used with such systems.

Processes Affected:
510(k), PMA, IDE, PDP, HDE, Design Control Input, Quality System Regulation

Type of Standard:
Vertical, National

Extent of Recognition:
Complete standard.

Related CFR Citations and Product Codes:

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<td>Electrode, Cutaneous</td>
<td>Class 2</td>
<td>GXY</td>
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<tr>
<td>§882.1400</td>
<td>Full-Montage Standard Electroencephalograph</td>
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<td>GWO</td>
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Reduced- Montage Standard Electroencephalograph Class 2
Recognized Consensus Standards

§882.1400 Device, Biofeedback

§882.5050 Device, Biofeedback

Class 2 HCC

Relevant Guidance:

"Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities: FDA Reviewer Guidance," April 1996


21 CFR 898 (Performance Standard For Electrode Lead Wires And Patient Cables)


"For Industry And FDA Staff Guidance On Electrosurgical Devices And The Application Of The Performance Standard Or Electrode Lead Wires And Patient Cables," November 1999

"Guidance For Industry And Food And Drug Administration Staff - Class II Special Controls Guidance Document: Electrocardiograph Electrodes," July 2011

FDA Technical Contact:

Michael Hoffmann
FDA/CDRH/ODE
10903 New Hampshire Avenue Building 66, Room 1434
Silver Spring MD 20993
301/796-6476
e-mail: michael.hoffmann@fda.hhs.gov

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