Recognized Consensus Standards

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

Part B: Supplementary Information

Recognition Number 17-13: IEEE Std 2010-2012, Recommended Practice For Neurofeedback Systems. (Neurology)

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:

Regulation Number	Device Name	Device Class	Product Code
§882.1320[23]	Electrode, Cutaneous	Class 2	GXY[24]
§882.1400[25]	Full-Montage Standard Electroencephalograph	Class 2	GWQ[26]
	Reduced- Montage Standard Electroencephalograph	Class 2	

§882.1400[27]	OMC[28]
§882.5050[29]	Device, Biofeedback — Class 2 — HCC[30]

Relevant Guidance:

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

ISO 10993-1 Fourth Edition 2009-10-15, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process

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

"Guidance Document On The Performance Standard For Electrode Lead Wires And Patient Cables," March 1998

Http://Www.Fda.Gov/Ohrms/Dockets/98fr/980448gd.Pdf

"For Industry And FDA Staff Guidance1 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

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23. ../cfcfr/cfrsearch.cfm?fr=882.1320
24. ../cfpcd/classification.cfm?start_search=1&productcode=GXY
25. ../cfcfr/cfrsearch.cfm?fr=882.1400
26. ../cfpcd/classification.cfm?start_search=1&productcode=GWQ
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28. ../cfpcd/classification.cfm?start_search=1&productcode=OMC
29. ../cfcfr/cfrsearch.cfm?fr=882.5050
30. ../cfpcd/classification.cfm?start_search=1&productcode=HCC

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

U.S. Department of Health & Human Services

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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23. ../cfcfr/cfrsearch.cfm?fr=882.1320
24. ../cfpcd/classification.cfm?start_search=1&productcode=GXY
25. ../cfcfr/cfrsearch.cfm?fr=882.1400
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