Product Classification

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Device	Device, Biofeedback
Regulation Description	Biofeedback device.
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	HCC
Premarket Review	Office of Device Evaluation [6] (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Neurodiagnostic and Neurosurgical Devices Branch (NNDB)
Submission Type	510(K) Exempt
Regulation Number	882.5050[7]
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of Class II (special controls) devices[9] subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.

Recognized Consensus Standard

- IEEE Std 2010-2012 Recommended Practice for Neurofeedback Systems[10]

Third Party Review	Not Third Party Eligible

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Page Last Updated: 03/09/2015

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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