Product Classification

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Device	Cuff, Nerve
Regulation Medical Specialty	Neurology
Review Panel	Neurology
Product Code	JXI
Premarket Review	Neurological and Physical Medicine Devices[6] (OHT5) Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)
Submission Type	510(k)
Regulation Number	882.5275
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[7]
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	Yes
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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6. https://www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization#OHT5
7. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=3883

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