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## Product Classification

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<b>Device</b>	Cuff, Nerve
<b>Regulation Medical Specialty</b>	Neurology
<b>Review Panel</b>	Neurology
<b>Product Code</b>	JXI
<b>Premarket Review</b>	<a href="#">Neurological and Physical Medicine Devices</a> <sup>6</sup> (OHT5) Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)
<b>Submission Type</b>	510(k)
<b>Regulation Number</b>	882.5275
<b>Device Class</b>	2
<b>Total Product Life Cycle (TPLC)</b>	<a href="#">TPLC Product Code Report</a> <sup>7</sup>
<b>GMP Exempt?</b>	No
<b>Summary Malfunction Reporting</b>	Eligible
<b>Implanted Device?</b>	Yes
<b>Life-Sustain/Support Device?</b>	No
<b>Third Party Review</b>	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>

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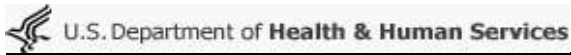


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