

K190801 PressOn Electrode HeadsetJul 10, 2019
103 days to decisionK190801 · Product code: **GXZ** · Neurology
Source: <https://www.510kdatabase.net/k190801/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle (GXZ)
Date received	Mar 29, 2019
Decision date	Jul 10, 2019
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	RhythmLink International, LLC
Location	Cayce, SC, US
Contact	Gabriel Orsinger
510(k) history	18 submissions · 18 cleared · 2002-2021

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