

**K112435 RHYTHMLINK MONOPOLAR STIMULATING
INSTRUMENT**Sep 22, 2011
29 days to decisionK112435 · Product code: **ETN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k112435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve (ETN)
Date received	Aug 24, 2011
Decision date	Sep 22, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112435/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026