

**K091056 RHYTHMLINK DISPOSABLE MONOPOLAR EMG
NEEDLE, MODEL TFDN26032252R**Jun 23, 2009
71 days to decisionK091056 · Product code: **IKT** · Neurology
Source: <https://www.510kdatabase.net/k091056/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Apr 13, 2009
Decision date	Jun 23, 2009
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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