FDA 510(k) Premarket Notification

K120342 EMG RECORDING ELECTRODE ASSEMBLY

CLEARED

Jun 22, 2012
140 days to decision

K120342 · Product code: **IKT** · Neurology
Source: https://www.510kdatabase.net/k120342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Needle, Diagnostic Electromyograph (IKT)
Date received	Feb 3, 2012
Decision date	Jun 22, 2012
Days to decision	140 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