K123902 PHYSICAL MONITORING REGISTRATION UNIT-S (PMRU-S)

CLEARED

Sep 13, 2013
269 days to decision

K123902 · Product code: **IKN** · Neurology
Source: https://www.510kdatabase.net/k123902/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electromyograph, Diagnostic (IKN)
Date received	Dec 18, 2012
Decision date	Sep 13, 2013
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oktx, LLC**
Location	Tulsa, OK, US
Contact	MARY ROSE C REASTON
510(k) history	1 submissions · 1 cleared · 2013-2013