FDA 510(k) Premarket Notification

K151784 ActTrust

CLEARED

May 25, 2016
329 days to decision

K151784 · Product code: **LEL** · Neurology
Source: https://www.510kdatabase.net/k151784/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sleep Assessment (LEL)
Date received	Jul 1, 2015
Decision date	May 25, 2016
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Condor Instruments Ltda. - Epp**
Location	Sao Paulo, BR
Contact	RODRIGO TREVISAN OKAMOTO
510(k) history	1 submissions · 1 cleared · 2016-2016