FDA 510(k) Premarket Notification

K180222 Reaxon Plus

CLEARED

Apr 24, 2018
89 days to decision

K180222 · Product code: **JXI** · Neurology
Source: https://www.510kdatabase.net/k180222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Jan 25, 2018
Decision date	Apr 24, 2018
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medovent GmbH**
Location	Mainz, DE
Contact	Peter Meier
510(k) history	2 submissions · 2 cleared · 2015-2018