FDA 510(k) Premarket Notification

K180206 neuromate Gen III

CLEARED

Apr 24, 2018
90 days to decision

K180206 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k180206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jan 24, 2018
Decision date	Apr 24, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Renishaw Mayfield Sarl**
Location	Chassieu, FR
Contact	Stephane Vinot
510(k) history	3 submissions · 3 cleared · 2014-2018