FDA 510(k) Premarket Notification

CLEARED

K150220 STM 9000 Basic, STM 9000 Standard, STM 9000 Fast, STM 9000 Ultra-Fast

Aug 19, 2015
201 days to decision

K150220 · Product code: **GWF** · Neurology
Source: https://www.510kdatabase.net/k150220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jan 30, 2015
Decision date	Aug 19, 2015
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eb Neuro S.P.A.**
Location	Indianpolis, IN, US
Contact	Christiano Pineider
510(k) history	13 submissions · 13 cleared · 2001-2024