FDA 510(k) Premarket Notification

K162873 MEP Monitor

CLEARED

Mar 31, 2017
169 days to decision

K162873 · Product code: **GWF** · Neurology
Source: https://www.510kdatabase.net/k162873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Oct 13, 2016
Decision date	Mar 31, 2017
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tonica Elektronik A/S**
Location	Farum, DK
Contact	LISE TERKELSEN
510(k) history	17 submissions · 17 cleared · 2006-2025