FDA 510(k) Premarket Notification

K152547 DNAP Electrode

CLEARED

Mar 4, 2016
178 days to decision

K152547 · Product code: **GZL** · Neurology
Source: https://www.510kdatabase.net/k152547/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Sep 8, 2015
Decision date	Mar 4, 2016
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ad-Tech Medical Instrument Corporation**
Location	Racine, WI, US
Contact	Lisa Theama
510(k) history	8 submissions · 8 cleared · 2016-2023