FDA 510(k) Premarket Notification

K162460 WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts

CLEARED

Apr 28, 2017
238 days to decision

K162460 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k162460/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 2, 2016
Decision date	Apr 28, 2017
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wavi Co.**
Location	Englewood, CO, US
Contact	ALEXIS VERACRUZ
510(k) history	2 submissions · 2 cleared · 2017-2022