FDA 510(k) Premarket Notification

K190416 Dome Electrode

CLEARED

Apr 4, 2019
42 days to decision

K190416 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k190416/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Cutaneous (GXY)
Date received	Feb 21, 2019
Decision date	Apr 4, 2019
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Coapt, LLC**
Location	Chicago, IL, US
Contact	Blair Lock
510(k) history	3 submissions · 3 cleared · 2017-2019