FDA 510(k) Premarket Notification

K162891 Complete Control System

CLEARED

Apr 14, 2017
179 days to decision

K162891 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k162891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Oct 17, 2016
Decision date	Apr 14, 2017
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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