FDA 510(k) Premarket Notification

K172503 MR Conditional Cup Electrode, MR Conditional Webb Electrode

CLEARED

Dec 1, 2017
105 days to decision

K172503 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k172503/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 18, 2017
Decision date	Dec 1, 2017
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rhythmlink International, LLC**
Location	Cayce, SC, US
Contact	Daniel McCoy
510(k) history	18 submissions · 18 cleared · 2002-2021