FDA 510(k) Premarket Notification

K200540 BRAINSTREAM Disposable Deep Cup EEG Electrodes

CLEARED

Jun 1, 2020
90 days to decision

K200540 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k200540/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Mar 3, 2020
Decision date	Jun 1, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Conmed Corporation**
Location	Utica, NY, US
Contact	Tessa Hopsicker
Website	https://www.conmed.com
510(k) history	83 submissions · 83 cleared · 2004-2026

Conmed Corporation is a global medical device manufacturer specializing in surgical equipment and operating room solutions. The company operates with a manufacturing facility in Utica, US, and serves multiple surgical specialties including general surgery, orthopedics, and patient monitoring. Conmed has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The company maintains active regulatory engagement, with its most recent clearance in 2026. Its cleared devices focus primarily on General & Plastic Surgery applications, including ele...