FDA 510(k) Premarket Notification

K203827 REMI

CLEARED

Mar 29, 2021
90 days to decision

K203827 · Product code: **OMC** · Neurology
Source: https://www.510kdatabase.net/k203827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Dec 29, 2020
Decision date	Mar 29, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Epitel, Inc.**
Location	Salt Lake City, UT, US
Contact	Mark Lehmkuhle
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**leanRAQA**
Contact	John Pappan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov