

**K234080 MEGA-IOM system with Neuro-IOM.NET software (32/B
- 32/S - 16/S)**Mar 25, 2024
94 days to decisionK234080 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k234080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Dec 22, 2023
Decision date	Mar 25, 2024
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Soterix Medical, Inc.
Location	Woodbridge, NJ, US
Contact	Danielle Dadona
510(k) history	6 submissions · 6 cleared · 2017-2026

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