

K192823 MEGA-TMSAug 13, 2021
681 days to decisionK192823 · Product code: **GWF** · Neurology
Source: <https://www.510kdatabase.net/k192823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Oct 2, 2019
Decision date	Aug 13, 2021
Days to decision	681 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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