

K233751 Milieve (YPS-301BD)Jun 3, 2024
194 days to decisionK233751 · Product code: **PCC** · Neurology
Source: <https://www.510kdatabase.net/k233751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (PCC)
Date received	Nov 22, 2023
Decision date	Jun 3, 2024
Days to decision	194 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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