

K182436 POWEREASE SystemOct 4, 2018
27 days to decisionK182436 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k182436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 7, 2018
Decision date	Oct 4, 2018
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Sofamor Danek USA, Inc.
Location	Memphis, TN, US
Contact	Ankit K. Shah
510(k) history	170 submissions · 159 cleared · 2000-2026

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