

**K111520 IPC POWEREASE SYSTEM**Oct 26, 2011  
146 days to decisionK111520 · Product code: **HBE** · Neurology  
Source: <https://www.510kdatabase.net/k111520/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Jun 2, 2011
Decision date	Oct 26, 2011
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Xomed, Inc.</b>
Location	Jacksonville, FL, US
Contact	RISHI SINHA
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
510(k) history	37 submissions · 37 cleared · 2001-2026

Medtronic Xomed, Inc. is a medical device manufacturer based in Jacksonville, US. The company specializes in ear, nose, and throat surgical devices and related technologies. Medtronic Xomed has maintained a strong FDA 510(k) regulatory record since 2001. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. The latest clearance was granted in 2026, demonstrating continued active development and market presence in specialized surgical instrumentation. The company's cleared device portfolio focuses primarily on ear, nose, and thr...

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