

**K081475 ELECTRIC DRILL SYSTEM [XPS 4000 SYSTEM, MIDAS REX LEGEND EHS SYSTEM, INTEGRATED POWER CONSOLE (IPC)]**Oct 17, 2008  
143 days to decisionK081475 · Product code: **HBE** · Neurology  
Source: <https://www.510kdatabase.net/k081475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	May 27, 2008
Decision date	Oct 17, 2008
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Xomed, Inc.</b>
Location	Jacksonville, FL, US
Contact	ANTOINE KOUCHAKJY
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...