

**K010677 XPS 3000 SYSTEM**May 7, 2001  
61 days to decisionK010677 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k010677/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Mar 7, 2001
Decision date	May 7, 2001
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Xomed, Inc.</b>
Location	Jacksonville, FL, US
Contact	MARTIN D SARGENT
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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