FDA 510(k) Premarket Notification

K022370 FRAMELOCK

CLEARED

Oct 18, 2002
88 days to decision

K022370 · Product code: **HBG** · Neurology
Source: https://www.510kdatabase.net/k022370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (manual) (HBG)
Date received	Jul 22, 2002
Decision date	Oct 18, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary
Other names	FRAMELOCK ACCESSORIES

APPLICANT

Company	**Medtronic Xomed, Inc.**
Location	Jacksonville, FL, US
Contact	B.L. MCDERMOTT
Website	https://www.medtronic.com
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...