FDA 510(k) Premarket Notification

K011321 MODIFICATION TO XPS 3000 SYSTEM

CLEARED

Jun 26, 2001
60 days to decision

K011321 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k011321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Apr 27, 2001
Decision date	Jun 26, 2001
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Xomed, Inc.**
Location	Jacksonville, FL, US
Contact	MARTIN D SARGENT
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...