

K081277 XPS 4000 SYSTEM, MIDAS REX LEGEND EHS SYSTEM, INTEGRATED POWER CONSOLE (IPC)

Sep 5, 2008
123 days to decision

K081277 · Product code: ERL · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k081277/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	May 5, 2008
Decision date	Sep 5, 2008
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Xomed, Inc.
Location	Jacksonville, FL, US
Contact	ANTOINE KOUCHAKJY
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...