

K132297 EM SINUS DILATION SYSTEMNov 5, 2013
104 days to decisionK132297 · Product code: **LRC** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k132297/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jul 24, 2013
Decision date	Nov 5, 2013
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Xomed, Inc.
Location	Jacksonville, FL, US
Contact	ROZANNE PACIEJ
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...
