FDA 510(k) Premarket Notification

K112686 NEXT GEN EMG ENDOTRACHEAL TUBE

CLEARED

Jun 27, 2012
286 days to decision

K112686 · Product code: **ETN** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k112686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Sep 15, 2011
Decision date	Jun 27, 2012
Days to decision	286 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Xomed, Inc.**
Location	Jacksonville, FL, US
Contact	MAREK PAWLOWSKI
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...