

K230320 NIM Standard Reinforced EMG Endotracheal TubeOct 26, 2023
262 days to decisionK230320 · Product code: **ETN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k230320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve (ETN)
Date received	Feb 6, 2023
Decision date	Oct 26, 2023
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CONTACT Reinforced EMG Endotracheal Tube

APPLICANT

Company	Medtronic Xomed, Inc.
Location	Jacksonville, FL, US
Contact	Alexandra Oliver
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...