FDA 510(k) Premarket Notification

CLEARED

K251672 NIM Essence™ EMG Endotracheal Tube (NIMEID060)

Feb 10, 2026
256 days to decision

K251672 · Product code: **ETN** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k251672/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	May 30, 2025
Decision date	Feb 10, 2026
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NIM Essence™ EMG Endotracheal Tube (NIMEID065); NIM Essence™ EMG Endotracheal Tube (NIMEID070); NIM Essence™ EMG Endotracheal Tube (NIMEID075); NIM Essence™ EMG Endotracheal Tube (NIMEID080)

APPLICANT

Company	**Medtronic Xomed, Inc.**
Location	Jacksonville, FL, US
Contact	Emily Davis
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...