FDA 510(k) Premarket Notification

K070886 MEROGEL INJECTABLE BIORESORBABLE STENT

CLEARED

Apr 26, 2007
27 days to decision

K070886 · Product code: **NHB** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k070886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer, Ear, Nose And Throat, Synthetic, Absorbable (NHB)
Date received	Mar 30, 2007
Decision date	Apr 26, 2007
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	JAYME WILSON
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...