

**K192389 TYRX Absorbable Antibacterial Envelope (medium),
TYRX Absorbable Antibacterial Envelope (large)**Mar 27, 2020
206 days to decision

K192389 · Product code: FTL · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k192389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 3, 2019
Decision date	Mar 27, 2020
Days to decision	206 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Nancy Cameron
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,...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026