FDA 510(k) Premarket Notification

CLEARED

K180122 TYRX Neuro Absorbable Antibacterial Envelope (medium)

Jun 7, 2018
142 days to decision

K180122 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Jan 16, 2018
Decision date	Jun 7, 2018
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary
Other names	TYRX Neuro Absorbable Antibacterial Envelope (large)

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,...