CLEARED

K153038 Everest 20 Disposable Inflation Device, Everest 20 Survival Kit, Everest 30 Disposable Inflation Device, Everest 30 Survival Kit

Apr 13, 2016
177 days to decision

K153038 · Product code: **MAV** · Cardiovascular
Source: https://www.510kdatabase.net/k153038/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Syringe, Balloon Inflation (MAV)
Date received	Oct 19, 2015
Decision date	Apr 13, 2016
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	NISARG SHAH
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,...