FDA 510(k) Premarket Notification

CLEARED

K100432 POLYFIN INFUSION SET, MODELS MMT-165, MMT-365, MMT-366, MMT-312S AND MMT-312L AND SOF-SET INFUSION SETS

Jul 9, 2010
143 days to decision

K100432 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k100432/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 16, 2010
Decision date	Jul 9, 2010
Days to decision	143 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medtronic Minimed**
Location	Northridge, CA, US
Contact	MARK FAILLACE
Website	https://www.medtronicdiabetes.com
510(k) history	48 submissions · 43 cleared · 1986-2026

Medtronic Minimed is a diabetes management solutions company based in Northridge, US. The company specializes in insulin delivery and glucose monitoring technologies. Medtronic Minimed has received FDA 510(k) clearances from total submissions since 1986. The company's regulatory focus centers on General Hospital devices, which represent 92% of submissions. Recent clearances in 2026 demonstrate continued active development and regulatory engagement. The company's cleared device portfolio includes insulin infusion pumps, infusion sets, mobile applications for diabetes manag...