

K965208 POLYFIN EXTENSION SET, MODELS 126 AND 128Feb 26, 1997
61 days to decisionK965208 · Product code: **FPK** · General Hospital
Source: <https://www.510kdatabase.net/k965208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Fluid Delivery (FPK)
Date received	Dec 27, 1996
Decision date	Feb 26, 1997
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Minimed
Location	Northridge, CA, US
Contact	TERRANCE H GREGG
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...
