

**K954969 POLYFIN QR SUBCUTANEOUS INFUSION SET**Feb 22, 1996  
115 days to decisionK954969 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k954969/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 30, 1995
Decision date	Feb 22, 1996
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Minimed</b>
Location	Northridge, CA, US
Contact	TERRANCE H GREGG
Website	<a href="https://www.medtronicdiabetes.com">https://www.medtronicdiabetes.com</a>
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...

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