

**K964456 POLYFIN QR WITH WINGS INFUSION SETS, MODELS  
365, 366, AND 367**Jan 30, 1997  
85 days to decisionK964456 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k964456/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Nov 6, 1996
Decision date	Jan 30, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Minimed</b>
Location	Northridge, CA, US
Contact	DON SELVEY
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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