

**K864327 MODEL 304-S EXTERNAL MICRO-VOLUME INFUSION PUMP**Feb 6, 1987  
94 days to decisionK864327 · Product code: **FRW** · General Hospital  
Source: <https://www.510kdatabase.net/k864327/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scale, Patient (FRW)
Date received	Nov 4, 1986
Decision date	Feb 6, 1987
Days to decision	94 days
Third-party review	No

**APPLICANT**

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Company	<b>Medtronic Minimed</b>
Location	Northridge, CA, US
Contact	WILLIAM DUFFELL
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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