

K864517 MODEL 504-S EXTERNAL INFUSION PUMP FOR DIABETICSDec 12, 1986
25 days to decisionK864517 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k864517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Nov 17, 1986
Decision date	Dec 12, 1986
Days to decision	25 days
Third-party review	No

APPLICANT

Company	Medtronic Minimed
Location	Northridge, CA, US
Contact	WILLIAM H DUFFELL
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...

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