

**K041317 MODIFICATION TO MEDTRONIC MINIMED PARADIGM
MODEL 512 INSULIN PUMP**Jul 19, 2004
62 days to decisionK041317 · Product code: **LZG** · General Hospital
Source: <https://www.510kdatabase.net/k041317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Insulin (LZG)
Date received	May 18, 2004
Decision date	Jul 19, 2004
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medtronic Minimed
Location	Northridge, CA, US
Contact	MARK J FAILLACE
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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