

K100066 DIABETESMANAGER SYSTEM, DIABETESMANAGER-RX SYSTEM MODEL VERSION 1.1Jul 15, 2010
185 days to decisionK100066 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k100066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Jan 11, 2010
Decision date	Jul 15, 2010
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welldoc, Inc.
Location	Baltimore, MD, US
Contact	MALINDA PEEPLES
510(k) history	11 submissions · 11 cleared · 2010-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100066/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026