

K162225 WellDoc BlueStar (WellDoc DiabetesManager System and DiabetesManager-Rx System)Nov 22, 2016
106 days to decisionK162225 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k162225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Aug 8, 2016
Decision date	Nov 22, 2016
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	WellDoc, Inc.
Location	Baltimore, MD, US
Contact	Michele Livingston
510(k) history	11 submissions · 11 cleared · 2010-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162225/> 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