

K012259 MEDFUSION 2001 & 2010, MODEL N7215IWCSep 12, 2001
56 days to decisionK012259 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k012259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Jul 18, 2001
Decision date	Sep 12, 2001
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	National Custom Ent., Inc.
Location	Burnsville, MN, US
Contact	DON PELLETIER
510(k) history	12 submissions · 11 cleared · 1993-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012259/> 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 July 2, 2026