

K090087 MRIDIUM 3860 MRI INFUSION PUMP/MONITORING SYSTEMApr 7, 2009
84 days to decisionK090087 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k090087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jan 13, 2009
Decision date	Apr 7, 2009
Days to decision	84 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Iradimed Corporation
Location	Winter Park, FL, US
Contact	FRANCIS X CASEY
Website	http://www.iradimed.com/
510(k) history	7 submissions · 7 cleared · 2005-2025

Iradimed Corporation specializes in MRI-safe medical devices for patient care in magnetic resonance imaging environments. The company develops infusion pumps, patient monitoring systems, and ferrous metal detection solutions designed for use during MRI procedures. Iradimed operates with a manufacturing facility in Winter Park, Florida. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since its first clearance in 2005. All submissions have resulted in clearances, with no denials. The latest clearance in 2025 demo...

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Device record: <https://www.510kdatabase.net/k090087/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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