

K050301 MRIDIUM 3850 MRI PUMP SYSTEMMar 24, 2005
44 days to decisionK050301 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k050301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Feb 8, 2005
Decision date	Mar 24, 2005
Days to decision	44 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...
