

K242752 MRidium 3870 MRI Infusion Pump System (3870)May 28, 2025
258 days to decisionK242752 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k242752/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Sep 12, 2024
Decision date	May 28, 2025
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iradimed Corporation
Location	Winter Park, FL, US
Contact	Steven Kachelmeyer
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...