

**K180903 3880 MRI Patient Monitoring System**Mar 29, 2019  
357 days to decisionK180903 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180903/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Apr 6, 2018
Decision date	Mar 29, 2019
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iradimed Corporation</b>
Location	Winter Park, FL, US
Contact	Francis X. Casey
Website	<a href="http://www.iradimed.com/">http://www.iradimed.com/</a>
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...