FDA 510(k) Premarket Notification

CLEARED

K182900 3880 MRI Patient Monitoring System

Dec 14, 2018
59 days to decision

K182900 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k182900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Oct 16, 2018
Decision date	Dec 14, 2018
Days to decision	59 days
Third-party review	No
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k182900/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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