

K182276 MEDRAD MRXperion MR Injection System and MR Injection System Syringe Kit

Nov 1, 2018
71 days to decision

K182276 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k182276/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 22, 2018
Decision date	Nov 1, 2018
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Medical Care, Inc.
Location	Indianola, PA, US
Contact	Katie Dillon
510(k) history	9 submissions · 9 cleared · 2015-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182276/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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