

K143538 MRXperion MR Injection System, MRXperion MR Injection System Syringe KitAug 14, 2015
242 days to decisionK143538 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k143538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Dec 15, 2014
Decision date	Aug 14, 2015
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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