

K252891 MEDRAD MRXperion MR Injection System and MR Injection System Syringe KitFeb 13, 2026
155 days to decisionK252891 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k252891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 11, 2025
Decision date	Feb 13, 2026
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MEDRAD ISI2 Module (ISI2)

APPLICANT

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

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