

**K132928 MEDRAD MARK 7 ARTERION INJECTION SYSTEM /
SYRINGE, TWIST & GO SYRINGE**

Jan 23, 2014
127 days to decision

K132928 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k132928/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 18, 2013
Decision date	Jan 23, 2014
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medrad, Inc. / Bayer Medical Care, Inc.
Location	Indianola, PA, US
Contact	LISA A EWING
510(k) history	2 submissions · 2 cleared · 2013-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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