

K193028 MEDRAD Mark 7 Arterion Injection SystemDec 5, 2019
36 days to decisionK193028 · Product code: **DXT** · General Hospital
Source: <https://www.510kdatabase.net/k193028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 30, 2019
Decision date	Dec 5, 2019
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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