

**K192370 MEDRAD Stellant FLEX CT Injection System with
Certegra Workstation**Dec 13, 2019
105 days to decisionK192370 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k192370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 30, 2019
Decision date	Dec 13, 2019
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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