

K182273 MEDRAD Stellant FLEX CT Injection System with Certegra Workstation, MEDRAD Stellant FLEX Syringe Kits, MEDRAD Stellant CT Injection System with Certegra Workstation, MEDRAD Stellant Syringe Kits, MEDRAD Stellant Connector Tubing, P3T Cardiac, P3T PA, P3T Abdomen, ISI, Connect.CT

Nov 1, 2018
71 days to decision

K182273 · Product code: DXT · Cardiovascular
Source: <https://www.510kdatabase.net/k182273/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 22, 2018
Decision date	Nov 1, 2018
Days to decision	71 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.net

Device record: <https://www.510kdatabase.net/k182273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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