

K152978 DeRoyal Angiography KitsMar 25, 2016
168 days to decisionK152978 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k152978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 9, 2015
Decision date	Mar 25, 2016
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Deroyal Industries, Inc.
Location	Mchenry, IL, US
Contact	Elizabeth Wheeler
510(k) history	91 submissions · 88 cleared · 1984-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026