

K171646 ACISTCVi® Contrast Delivery SystemFeb 16, 2018
256 days to decisionK171646 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k171646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 5, 2017
Decision date	Feb 16, 2018
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acist Medical Systems, Inc.
Location	Eden Prairie, MN, US
Contact	Melissa Sommerfeld
510(k) history	14 submissions · 14 cleared · 2001-2024

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