

K252653 ACIST Pro Diagnostic System (019304)May 13, 2026
264 days to decisionK252653 · Product code: **DXT** · General Hospital
Source: <https://www.510kdatabase.net/k252653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 22, 2025
Decision date	May 13, 2026
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Processing Unit Bed Mount; AngioTouch Module; ACIST Pro Cart; Single Transducer Cable; Triple Transducer Cable

APPLICANT

Company	Acist Medical Systems, Inc.
Location	Eden Prairie, MN, US
Contact	Meg Daniel
510(k) history	16 submissions · 16 cleared · 2001-2026

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