

K233904 ACIST RXi System (016616)Jul 17, 2024
219 days to decisionK233904 · Product code: **DXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k233904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Dec 11, 2023
Decision date	Jul 17, 2024
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ACIST Navvus II Catheter (016675_

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233904/> 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 13, 2026