

K190473 ACIST RXi System and Navvus II CatheterSep 13, 2019
198 days to decisionK190473 · Product code: **OBI** · Cardiovascular
Source: <https://www.510kdatabase.net/k190473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Pressure Monitoring, Cardiac (OBI)
Date received	Feb 27, 2019
Decision date	Sep 13, 2019
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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