

**K191175 ACIST Kodama Intravascular Ultrasound Catheter,
ACIST HDi System**Jun 27, 2019
57 days to decisionK191175 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k191175/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	May 1, 2019
Decision date	Jun 27, 2019
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191175/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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