FDA 510(k) Premarket Notification

K173063 ACIST Kodama Intravascular Ultrasound Catheter, ACIST HDi System

CLEARED

Oct 23, 2017
24 days to decision

K173063 · Product code: **OBJ** · Cardiovascular
Source: https://www.510kdatabase.net/k173063/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Sep 29, 2017
Decision date	Oct 23, 2017
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k173063/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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