FDA 510(k) Premarket Notification

K191175 ACIST Kodama Intravascular Ultrasound Catheter, ACIST HDi System

CLEARED

Jun 27, 2019
57 days to decision

K191175 · 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