FDA 510(k) Premarket Notification

K172216 ACIST RXi Mini System

CLEARED

Aug 18, 2017
25 days to decision

K172216 · Product code: **DRQ** · Cardiovascular
Source: https://www.510kdatabase.net/k172216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Amplifier And Signal Conditioner, Transducer Signal (DRQ)
Date received	Jul 24, 2017
Decision date	Aug 18, 2017
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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