FDA 510(k) Premarket Notification

K033436 REPROCESSED DIAGNOSTIC ULTRASOUND CATHETER

CLEARED

Mar 16, 2005
505 days to decision

K033436 · Product code: **OWQ** · Cardiovascular
Source: https://www.510kdatabase.net/k033436/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reprocessed Intravascular Ultrasound Catheter (OWQ)
Date received	Oct 28, 2003
Decision date	Mar 16, 2005
Days to decision	505 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alliance Medical Corp.**
Location	Phoenix, AZ, US
Contact	MOIRA BARTON
510(k) history	36 submissions · 36 cleared · 2001-2007