

**K970049 BSC, SONICATH ULTRA IMAGING CATHETER
3.2F/20MHZ(37410/456221 & BSC, SONICATH ULTRA IMAGING
CATHETER 2.9F/20MHZ/37411/**

Jun 20, 1997
165 days to decision

K970049 · Product code: ITX · Radiology
Source: <https://www.510kdatabase.net/k970049/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jan 6, 1997
Decision date	Jun 20, 1997
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Imaging Systems, Inc.
Location	Sunnyvale, CA, US
Contact	STEVE JWANOUSKOS
510(k) history	19 submissions · 19 cleared · 1989-1997

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Device record: <https://www.510kdatabase.net/k970049/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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