

**K921631 CVIS INSIGHT IMAGING CATHETER FOR
INTRALUMINAL**Jul 2, 1992
87 days to decisionK921631 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k921631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 6, 1992
Decision date	Jul 2, 1992
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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