

**K911414 CVIS INSIGHT IMAGING CATHETERS**Sep 11, 1991  
163 days to decisionK911414 · Product code: **ITX** · Radiology  
Source: <https://www.510kdatabase.net/k911414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 1, 1991
Decision date	Sep 11, 1991
Days to decision	163 days
Third-party review	No

**APPLICANT**

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Company	<b>Cardiovascular Imaging Systems, Inc.</b>
Location	Sunnyvale, CA, US
Contact	RUSSELL W FELKEY
510(k) history	19 submissions · 19 cleared · 1989-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911414/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026