

**K973713 22 GAUGE P.D. ACCESS VASCULAR ACCESS DEVICE
(CATHETER/NEEDLE ASSEMBLY), 24 GAUGE P.D. ACCESS
VASCULAR ACCESS DEVICE (CAR**Jan 23, 1998
116 days to decisionK973713 · Product code: ITX · Radiology
Source: <https://www.510kdatabase.net/k973713/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Sep 29, 1997
Decision date	Jan 23, 1998
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Dynamics, Inc.
Location	Irvine, CA, US
Contact	PAMELA MISAJON
510(k) history	11 submissions · 11 cleared · 1994-1998

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