

K933073 HEARTTRACE LEFT VENTRICULAR ANALYSIS SOFTWAREOct 7, 1993
106 days to decisionK933073 · Product code: IZI · Radiology
Source: <https://www.510kdatabase.net/k933073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jun 23, 1993
Decision date	Oct 7, 1993
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Heartware Intl. Corp.
Location	New York, NY, US
Contact	CYNTHIA SINCLAIR
510(k) history	4 submissions · 4 cleared · 1989-1993

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