

**K933058 HEARTTRACK QUANTITATIVE CORONARY ANGIOGRAPHY SOFTW**

Sep 28, 1993  
98 days to decision

K933058 · Product code: IZI · Radiology  
Source: <https://www.510kdatabase.net/k933058/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jun 22, 1993
Decision date	Sep 28, 1993
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k933058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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