

**K953634 SHIMASONIC SDU-350 ELECTRONIC LINEAR/CONVEX
DIAGNOSTIC ULTRASOUND SYSTEM**

Feb 13, 1996
195 days to decision

K953634 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k953634/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Aug 2, 1995
Decision date	Feb 13, 1996
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shimadzu Medical Systems
Location	Gardena, CA, US
Contact	YASHUHARU ISHII
510(k) history	90 submissions · 90 cleared · 1989-2008

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k953634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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