

**K003515 ECHO VIEW/SHIMASONIC DIAGNOSTIC
ULTRASOUND SYSTEM, MODEL SDU-1200**Feb 12, 2001
90 days to decisionK003515 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k003515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Nov 14, 2000
Decision date	Feb 12, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003515/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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