

**K003514 ECHO VIEW/SHIMASONIC DIAGNOSTIC
ULTRASOUND SYSTEM, MODEL SDU-2200**

Feb 12, 2001
90 days to decision

K003514 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k003514/>

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.net

Device record: <https://www.510kdatabase.net/k003514/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026