

K082224 DIAGNOSTIC ULTRASOUND SYSTEM SARANO, ECHO VIEW, SHIMASONICDec 15, 2008
131 days to decisionK082224 · Product code: ITX · Radiology
Source: <https://www.510kdatabase.net/k082224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Aug 6, 2008
Decision date	Dec 15, 2008
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082224/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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