

K945389 IVR MASTERFeb 7, 1995
96 days to decisionK945389 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k945389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 3, 1994
Decision date	Feb 7, 1995
Days to decision	96 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shimadzu Corp.
Location	Mchenry, IL, US
Contact	MICHAEL FISHBACK
Website	http://www.shimadzu.com/
510(k) history	49 submissions · 49 cleared · 1979-2015

Shimadzu Corp. is a Japanese manufacturer of precision instruments and medical equipment, established in 1875 and based in Kyoto, Japan. The American division, Shimadzu Scientific Instruments, was founded in 1975 and operates from McHenry, US. Shimadzu has received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus centers on Radiology devices, which represent 98% of its FDA 510(k) portfolio. Clearances span from 1979 to 2015, establishing a long historical record in medical device regulation. Recent cleared ...
