

K854337 SDL-300Jun 20, 1986
235 days to decisionK854337 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k854337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Oct 28, 1985
Decision date	Jun 20, 1986
Days to decision	235 days
Third-party review	No

APPLICANT

Company	Shimadzu Corp.
Location	Mchenry, IL, US
Contact	TAKAO SOMEYAMA
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 ...
