

K973342 DAR-3000BOct 8, 1997
33 days to decisionK973342 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k973342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 5, 1997
Decision date	Oct 8, 1997
Days to decision	33 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 ...
