

K043379 SHIMADZU SURGICAL MOBILE C-ARM IMAGING X-RAY SYSTEM, MODEL WHA-200Feb 17, 2005
71 days to decisionK043379 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k043379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Dec 8, 2004
Decision date	Feb 17, 2005
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shimadzu Corp.
Location	Mchenry, IL, US
Contact	RANDAL WALKER
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 ...