FDA 510(k) Premarket Notification

K032443 DIGITAL ANGIOGRAPHY SYSTEM DIGITEX SAFIRE

CLEARED

Feb 20, 2004
196 days to decision

K032443 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k032443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Angiographic (IZI)
Date received	Aug 8, 2003
Decision date	Feb 20, 2004
Days to decision	196 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Shimadzu Corp.**
Location	Mchenry, IL, US
Contact	TAKESHI OZAKI
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 ...