

**K062360 BRANSIST SAFIRE**Oct 5, 2006  
52 days to decisionK062360 · Product code: **IZI** · Radiology  
Source: <https://www.510kdatabase.net/k062360/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Angiographic (IZI)
Date received	Aug 14, 2006
Decision date	Oct 5, 2006
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shimadzu Corp.</b>
Location	Mchenry, IL, US
Contact	RANDAL WALKER
Website	<a href="http://www.shimadzu.com/">http://www.shimadzu.com/</a>
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 ...

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