

**K982583 SHIMADZU WHOLE BODY X-RAY COMPUTED TOMOGRAPHY SCANNER SCT-6800TXL**Oct 5, 1998  
73 days to decisionK982583 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k982583/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 24, 1998
Decision date	Oct 5, 1998
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shimadzu Corp.</b>
Location	Mchenry, IL, US
Contact	MICHAEL FISHBACK
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 ...