

**K080701 SHIMADZU MOBILE X-RAY SYSTEM MOBILE DART EVOLUTION**May 14, 2008  
64 days to decisionK080701 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k080701/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 11, 2008
Decision date	May 14, 2008
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shimadzu Corp.</b>
Location	Mchenry, IL, US
Contact	DON KARLE
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 ...