

K895394 MOBILE X-RAY TELEVISION UNIT WHA-10A/BNov 13, 1989
68 days to decisionK895394 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k895394/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received | Sep 6, 1989 |
| Decision date | Nov 13, 1989 |
| Days to decision | 68 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Shimadzu Corp. |
| Location | Mchenry, IL, US |
| Contact | MASAO YOSHIMURA |
| 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 ...
