

K131075 X-RAY TV SYSTEM SONIAL VISION G4Mar 28, 2014
345 days to decisionK131075 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k131075/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | System, X-ray, Fluoroscopic, Image-intensified (JAA) |
| Date received | Apr 17, 2013 |
| Decision date | Mar 28, 2014 |
| Days to decision | 345 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shimadzu Corp. |
| Location | Mchenry, IL, US |
| Contact | DON KARLE |
| 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 ...
