

K101036 SHIMADZU COLLIMATOR R-20JAug 26, 2010
134 days to decisionK101036 · Product code: **IZX** · Radiology
Source: <https://www.510kdatabase.net/k101036/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Collimator, Manual, Radiographic (IZX) |
| Date received | Apr 14, 2010 |
| Decision date | Aug 26, 2010 |
| Days to decision | 134 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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