

K837314 SDL-10 DIAGNOSTIC ULTRASOUNDApr 29, 1983
38 days to decision

K837314 · Radiology

Source: <https://www.510kdatabase.net/k837314/>**SUBMISSION DETAILS**

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|--------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Date received | Mar 22, 1983 |
| Decision date | Apr 29, 1983 |
| Days to decision | 38 days |
| Third-party review | No |

APPLICANT

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