

**K193183 ACIST HDi System, ACIST Kodama Intravascular
Ultrasound Catheter**

Mar 20, 2020
123 days to decision

K193183 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k193183/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Ultrasound, Intravascular (OBJ) |
| Date received | Nov 18, 2019 |
| Decision date | Mar 20, 2020 |
| Days to decision | 123 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Acist Medical Systems, Inc. |
| Location | Eden Prairie, MN, US |
| Contact | Angela Johnson |
| 510(k) history | 14 submissions · 14 cleared · 2001-2024 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193183/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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