

K113008 KODAMA INTRAVASCULAR ULTRASOUND CATHETERJun 14, 2012
251 days to decisionK113008 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k113008/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Ultrasound, Intravascular (OBJ) |
| Date received | Oct 7, 2011 |
| Decision date | Jun 14, 2012 |
| Days to decision | 251 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Silicon Vally Medical Instruments, Inc. |
| Location | Fremont, CA, US |
| Contact | RICHARD E ANDERSON |
| 510(k) history | 3 submissions · 3 cleared · 2011-2013 |

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