

**K082061 INQUIRY H-CURVE TV STEERABLE DIAGNOSTIC  
CATHETER**Aug 19, 2008  
29 days to decisionK082061 · Product code: **DRF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082061/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Special  |
| Device classification | Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF) |
| Date received         | Jul 21, 2008   |
| Decision date         | Aug 19, 2008   |
| Days to decision      | 29 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Irvine Biomedical, Inc.</b>          |
| Location       | Irvine, CA, US                          |
| Contact        | JEANETTE HENDRICKSON                    |
| 510(k) history | 11 submissions · 11 cleared · 1995-2008 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026