

**K033199 COMPACT DIGITAL CARDIAC CAMERA (CDCC)**Nov 12, 2003  
41 days to decisionK033199 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k033199/>**SUBMISSION DETAILS**

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|                       |                                              |
|-----------------------|----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received         | Oct 2, 2003                                  |
| Decision date         | Nov 12, 2003                                 |
| Days to decision      | 41 days                                      |
| Third-party review    | No                                           |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Is2 Medical Systems, Inc.</b>      |
| Location       | Ottawa, Ontario, CA                   |
| Contact        | VICTOR WOODBURN                       |
| 510(k) history | 1 submissions · 1 cleared · 2003-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033199/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026