

K041294 BIOZDX HEMODYNAMIC MONITORDec 8, 2004
208 days to decisionK041294 · Product code: **DSB** · CardiovascularSource: <https://www.510kdatabase.net/k041294/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plethysmograph, Impedance (DSB) |
| Date received | May 14, 2004 |
| Decision date | Dec 8, 2004 |
| Days to decision | 208 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cardiodynamics International Corp. |
| Location | San Diego, CA, US |
| Contact | DENNIS HEPP |
| 510(k) history | 11 submissions · 11 cleared · 1996-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041294/> 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 23, 2026