

K053104 DIMENSION CARDIOPHASE HIGH SENSITIVITY C-REACTIVE PROTEIN CALIBRATORDec 23, 2005
49 days to decisionK053104 · Product code: **JIS** · Chemistry
Source: <https://www.510kdatabase.net/k053104/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Primary (JIS) |
| Date received | Nov 4, 2005 |
| Decision date | Dec 23, 2005 |
| Days to decision | 49 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dade Behring, Inc. |
| Location | Newark,, DE, US |
| Contact | ANDREA M TASKER |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053104/>; 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 19, 2026