

**K152582 CORE FM System, Patient Interface Module (OPIM),
Hemodynamic Converter Box**Dec 3, 2015
84 days to decisionK152582 · Product code: **DSK** · Cardiovascular
Source: <https://www.510kdatabase.net/k152582/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Computer, Blood-pressure (DSK) |
| Date received | Sep 10, 2015 |
| Decision date | Dec 3, 2015 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Volcano Corporation |
| Location | Rancho Cordova,, CA, US |
| Contact | NATHAN DA SILVA |
| 510(k) history | 55 submissions · 55 cleared · 2005-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152582/> 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 May 14, 2026