

K243650 Zio® monitor (DFG0001)Aug 15, 2025
262 days to decisionK243650 · Product code: **DSH** · CardiovascularSource: <https://www.510kdatabase.net/k243650/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Recorder, Magnetic Tape, Medical (DSH) |
| Date received | Nov 26, 2024 |
| Decision date | Aug 15, 2025 |
| Days to decision | 262 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | iRhythm Technologies, Inc. |
| Location | San Francisco, CA, US |
| Contact | Kiran Sorathia |
| 510(k) history | 17 submissions · 17 cleared · 2008-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243650/> 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