

K170181 PrizmaSep 1, 2017
225 days to decisionK170181 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k170181/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transmitters And Receivers, Electrocardiograph, Telephone (DXH) |
| Date received | Jan 19, 2017 |
| Decision date | Sep 1, 2017 |
| Days to decision | 225 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | G-Medical Innovations , Ltd. |
| Location | Rehovot, IL |
| Contact | N. Epstein |
| 510(k) history | 2 submissions · 2 cleared · 2017-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170181/> 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 28, 2026