

**K243252 ZBPro Diagnostic**Jul 10, 2025  
268 days to decisionK243252 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k243252/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrocardiograph (DPS)           |
| Date received         | Oct 15, 2024                       |
| Decision date         | Jul 10, 2025                       |
| Days to decision      | 268 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Zbeats, Inc.</b>                   |
| Location       | Stony Brook, NY, US                   |
| Contact        | Bin Fang                              |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

**REGULATORY CONSULTANT**

---

|                 |                                   |
|-----------------|-----------------------------------|
| Consulting firm | <b>Zaliance Medical Solutions</b> |
| Contact         | Christopher Ford                  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243252/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026