

**K231335 Cleerly ISCHEMIA**Sep 8, 2023  
123 days to decisionK231335 · Product code: **QXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231335/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Adjunctive Epicardial Vascular Physiologic Status Indicator (QXZ) |
| Date received         | May 8, 2023   |
| Decision date         | Sep 8, 2023   |
| Days to decision      | 123 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Cleerly, Inc.</b>                  |
| Location       | New York, NY, US                      |
| Contact        | Candice Bautista-Biddle               |
| 510(k) history | 4 submissions · 4 cleared · 2019-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231335/> 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 26, 2026