

**K253306 BioTracker 2.0**Jun 26, 2026  
270 days to decision

K253306 · Cardiovascular

Source: <https://www.510kdatabase.net/k253306/>**SUBMISSION DETAILS**

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|                     |                                    |
|---------------------|------------------------------------|
| Decision            | Substantially Equivalent (Cleared) |
| Submission type     | Traditional                        |
| Date received       | Sep 29, 2025                       |
| Decision date       | Jun 26, 2026                       |
| Days to decision    | 270 days                           |
| Third-party review  | No                                 |
| Summary / Statement | Summary                            |

**APPLICANT**

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|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Biotracker, LLC</b>                |
| Location       | Miami, FL, US                         |
| Contact        | Breno Moreira                         |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253306/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 10, 2026