

K223929 Laguna™ Clot Retriever System and Malibu™ Aspiration Catheter System (Laguna Thrombectomy System)Jun 1, 2023
153 days to decisionK223929 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k223929/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Peripheral Mechanical Thrombectomy With Aspiration (QEW) |
| Date received | Dec 30, 2022 |
| Decision date | Jun 1, 2023 |
| Days to decision | 153 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Innova Vascular, Inc. |
| Location | Irvine, CA, US |
| Contact | Ryan Kenney |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223929/> 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 27, 2026