

K153502 ClariVein ICJan 6, 2016
30 days to decisionK153502 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k153502/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Continuous Flush (KRA) |
| Date received | Dec 7, 2015 |
| Decision date | Jan 6, 2016 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vascular Insights, LLC |
| Location | Madison, CT, US |
| Contact | LORRAINE M. HANLEY |
| 510(k) history | 2 submissions · 2 cleared · 2008-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153502/> 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 3, 2026