

K160318 PlasmaFlowApr 1, 2016
56 days to decisionK160318 · Product code: **JOW** · Cardiovascular
Source: <https://www.510kdatabase.net/k160318/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Sleeve, Limb, Compressible (JOW) |
| Date received | Feb 5, 2016 |
| Decision date | Apr 1, 2016 |
| Days to decision | 56 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Manamed, Inc. |
| Location | Costa Mesa, CA, US |
| Contact | Trevor Theriot |
| 510(k) history | 7 submissions · 7 cleared · 2016-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160318/> 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 25, 2026