

**K143454 Pruitt F3-S Carotid Shunt**Aug 27, 2015  
267 days to decisionK143454 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k143454/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Catheter, Intravascular Occluding, Temporary (MJN) |
| Date received         | Dec 3, 2014  |
| Decision date         | Aug 27, 2015                                       |
| Days to decision      | 267 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>LeMaitre Vascular, Inc.</b>          |
| Location       | Burlington, MA, US                      |
| Contact        | Xiang Zhang                             |
| 510(k) history | 32 submissions · 32 cleared · 2003-2022 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143454/> 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 May 15, 2026