

**K061772 TRIACTIV FX EMBOLIC PROTECTION SYSTEM**Jul 11, 2006  
18 days to decisionK061772 · Product code: **NFA** · CardiovascularSource: <https://www.510kdatabase.net/k061772/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA) |
| Date received         | Jun 23, 2006  |
| Decision date         | Jul 11, 2006  |
| Days to decision      | 18 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Kensey Nash Corp.</b>                |
| Location       | Exton, PA, US                           |
| Contact        | ROBIN M FATZINGER                       |
| 510(k) history | 19 submissions · 19 cleared · 1993-2011 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061772/> 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 19, 2026