

**K112448 PULSIOFLEX**Sep 22, 2011  
28 days to decisionK112448 · Product code: **DXG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112448/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Special   |
| Device classification | Computer, Diagnostic, Pre-programmed, Single-function (DXG) |
| Date received         | Aug 25, 2011  |
| Decision date         | Sep 22, 2011  |
| Days to decision      | 28 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Pulsion Medical Systems, Inc.</b>  |
| Location       | Cornelius, NC, US                     |
| Contact        | Jamie Sulley                          |
| 510(k) history | 3 submissions · 3 cleared · 2000-2011 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112448/> 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 June 18, 2026