

**K082380 VICARDIO 12B**Dec 3, 2008  
106 days to decisionK082380 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082380/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrocardiograph (DPS)           |
| Date received         | Aug 19, 2008                       |
| Decision date         | Dec 3, 2008                        |
| Days to decision      | 106 days                           |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Energy-Lab Technologies GmbH</b>   |
| Location       | Hasbrouck Heights, NJ, US             |
| Contact        | GEORGE MYERS                          |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082380/> 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 24, 2026