

**K111055 GALAXY SYSTEM**Dec 21, 2011  
250 days to decisionK111055 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k111055/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                       |
| Submission type       | Traditional  |
| Device classification | Standard Polysomnograph With Electroencephalograph (OLV) |
| Date received         | Apr 15, 2011   |
| Decision date         | Dec 21, 2011   |
| Days to decision      | 250 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |
| Other names           | JUPITER  |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Personal Health Institute International</b> |
| Location       | Battle Creek, MI, US                           |
| Contact        | KUMAR KULKARNI                                 |
| 510(k) history | 1 submissions · 1 cleared · 2011-2011          |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k111055/> 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 15, 2026