

**K241665 Omni Legend**Aug 8, 2024  
59 days to decisionK241665 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k241665/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received         | Jun 10, 2024                                 |
| Decision date         | Aug 8, 2024                                  |
| Days to decision      | 59 days                                      |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Ge Medical Systems Israel, Functional Imaging</b> |
| Location       | Tirat Hacarmel, IL                                   |
| Contact        | Alexandra Lifshits                                   |
| 510(k) history | 4 submissions · 4 cleared · 2010-2025                |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241665/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026