

**K241717 E1000 Dx Digital Pathology Solution**Feb 28, 2025  
259 days to decisionK241717 · Product code: **PSY** · Pathology  
Source: <https://www.510kdatabase.net/k241717/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Whole Slide Imaging System (PSY)   |
| Date received         | Jun 14, 2024                       |
| Decision date         | Feb 28, 2025                       |
| Days to decision      | 259 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Shandon Diagnostics Limited</b>    |
| Location       | Runcorn, GB                           |
| Contact        | Naveen Kaki                           |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241717/>; 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 13, 2026