

**K250224 handLITE (TN19S)**Apr 18, 2025  
81 days to decisionK250224 · Product code: **ONE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250224/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | Powered Light Based Non-laser Surgical Instrument (ONE) |
| Date received         | Jan 27, 2025  |
| Decision date         | Apr 18, 2025  |
| Days to decision      | 81 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>iSMART Developments, Ltd.</b>      |
| Location       | Birmingham, GB                        |
| Contact        | Susan D&apos;Arcy                     |
| 510(k) history | 3 submissions · 3 cleared · 2023-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250224/> 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 14, 2026