

K160968 iPulse SmoothSkin Gold Hair Removal DeviceApr 14, 2016
8 days to decisionK160968 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160968/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Light Based Over-the-counter Hair Removal (OHT) |
| Date received | Apr 6, 2016 |
| Decision date | Apr 14, 2016 |
| Days to decision | 8 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cyden Limited |
| Location | Swansea, Wales, GB |
| Contact | MIKE KIERNAN |
| 510(k) history | 21 submissions · 21 cleared · 2004-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160968/> 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 27, 2026