

K162231 iPulse SmoothSkin Gold Hair Removal Device, Venus Silk.expertNov 16, 2016
100 days to decisionK162231 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Aug 8, 2016
Decision date	Nov 16, 2016
Days to decision	100 days
Third-party review	No
Summary / Statement	Statement

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/k162231/> 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