

**K192010 SmoothSkin BARE+**Sep 24, 2019  
57 days to decisionK192010 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192010/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jul 29, 2019
Decision date	Sep 24, 2019
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cyden Limited</b>
Location	Swansea, Wales, GB
Contact	Adam Stephens
510(k) history	21 submissions · 21 cleared · 2004-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192010/> 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 27, 2026