

**K181734 Beurer IPL 8500 device/ IPL VelvetSkin Pro**Sep 19, 2018  
79 days to decisionK181734 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181734/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Light Based Over-the-counter Hair Removal (OHT) |
| Date received         | Jul 2, 2018                                     |
| Decision date         | Sep 19, 2018                                    |
| Days to decision      | 79 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Home Well Trading, Ltd.</b>        |
| Location       | Tortola, VG                           |
| Contact        | Martin Gurovich                       |
| 510(k) history | 2 submissions · 2 cleared · 2018-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181734/> 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 June 28, 2026