

**K222710 IPL Cooling Hair Removal Device**Dec 1, 2022  
84 days to decisionK222710 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222710/>**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         | Sep 8, 2022                                     |
| Decision date         | Dec 1, 2022                                     |
| Days to decision      | 84 days   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shenzhen Siken 3D Technology Development Co., Ltd.</b> |
| Location       | Shenzhen, CN  |
| Contact        | Jingquan Liu  |
| 510(k) history | 6 submissions · 6 cleared · 2017-2025                     |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Feiyang Drug &amp; Medical Consulting Technical Service Group</b> |
| Contact         | Rain Yip   |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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