

**K210119 IPL Hair Removal Device (Model: KCA423)**May 21, 2021  
122 days to decisionK210119 · Product code: **ONF** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k210119/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jan 19, 2021
Decision date	May 21, 2021
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Shenzhen Boyuan Intelligent Electronic Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Cheryl Yang
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Sgs-Cstc Standards Technical Services Co., Ltd.</b>
Contact	Iris Fung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210119/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026