

**K212099 Red Wave Hair Removal**Sep 24, 2021  
80 days to decisionK212099 · Product code: **ONF** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k212099/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jul 6, 2021
Decision date	Sep 24, 2021
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shenzhen Accompany Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Yourong Lai
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Guangdong Jianda Medical Technology Co., Ltd.</b>
Contact	Jett Lee

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212099/> 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 25, 2026