

K221214 Hand-held IPL device (IPL Home Use Hair Removal Device) Model:FZ-608, FZ-608G, FZ-100, FZ-200Sep 21, 2022
147 days to decisionK221214 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Apr 27, 2022
Decision date	Sep 21, 2022
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Ionka Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Chen Dongfa
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen CT Bio-Tech Co., Ltd.
Contact	Amos Zou

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.netDevice record: <https://www.510kdatabase.net/k221214/> 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 26, 2026