

K212907 Aimanfun Lumea Comfort, A-2789/A-3588Dec 2, 2021
80 days to decisionK212907 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Sep 13, 2021
Decision date	Dec 2, 2021
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kam Yuen Plastic Products , Ltd.
Location	Zhongshan, CN
Contact	Anna Dan
510(k) history	5 submissions · 5 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Guangdong Jianda Medical Technology Co., Ltd.
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.netDevice record: <https://www.510kdatabase.net/k212907/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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