

K221770 Fiber Laser Treatment SystemOct 13, 2022
114 days to decisionK221770 · Product code: **ONG** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Jun 21, 2022
Decision date	Oct 13, 2022
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Apolo Medical Technology Co., Ltd.
Location	Shanghai, CN
Contact	Felix Li
510(k) history	13 submissions · 13 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221770/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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