

K191349 980nm Diode Laser Therapy DeviceAug 16, 2019
88 days to decisionK191349 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 20, 2019
Decision date	Aug 16, 2019
Days to decision	88 days
Third-party review	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

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