

K203395 Platform treatment systemJan 28, 2022
436 days to decisionK203395 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k203395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 18, 2020
Decision date	Jan 28, 2022
Days to decision	436 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

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