

K221597 CO2 Laser SystemSep 15, 2022
105 days to decisionK221597 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 2, 2022
Decision date	Sep 15, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smedtrum Medical Technology Co., Ltd.
Location	New Taipei City, TW
Contact	Crimson Wu
510(k) history	5 submissions · 5 cleared · 2022-2024

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