

K192528 CO2 Laser Therapy SystemDec 3, 2019
81 days to decisionK192528 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 13, 2019
Decision date	Dec 3, 2019
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shangdong Huamei Technology Co., Ltd.
Location	Weifang, CN
Contact	Xu QingHua
510(k) history	5 submissions · 5 cleared · 2019-2023

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