

K243465 Diode Laser Hair Removal Device (EVOLUTION MEDICAL)Feb 6, 2025
90 days to decisionK243465 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2024
Decision date	Feb 6, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diode Laser Hair Removal Device (M-I-X MEDICAL); Diode Laser Hair Removal Device (GENESIS); Diode Laser Hair Removal Device (Lotus); Diode Laser Hair Removal Device (Ultimate)

APPLICANT

Company	Guangzhou Chuang Zao Mei Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Sergei Slashchilin
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Askway Innovative , Ltd.
Contact	Asher William

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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