FDA 510(k) Premarket Notification

CLEARED

K243141 Diode Laser System (LaserPro D 980)

Dec 26, 2024
87 days to decision

K243141 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2024
Decision date	Dec 26, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diode Laser System (LaserPro D 810); Diode Laser System (Aurolance 980); Diode Laser System (Aurolance 810); Diode Laser System (Aurolance AM)

APPLICANT

Company	**Jiangxi Medex Technology Co., Ltd.**
Location	Jiangxi, CN
Contact	Zhang Kaixia
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Microkn Medical Technology Service (Shanghai) Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov