FDA 510(k) Premarket Notification

K223778 Diode Laser Hair Removal System (RD-SLD600)

CLEARED

Mar 31, 2023
105 days to decision

K223778 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 16, 2022
Decision date	Mar 31, 2023
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Omni Laser Skinology Co., Ltd.**
Location	Shanghai, CN
Contact	Avril Ouyang
510(k) history	3 submissions · 3 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**New Risen Enterprise Management Consulting 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