FDA 510(k) Premarket Notification

K233224 Epilaser Pro

CLEARED

Jan 27, 2024
121 days to decision

K233224 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233224/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 28, 2023
Decision date	Jan 27, 2024
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Epilady 2000, LLC**
Location	Washington D.C., DC, US
Contact	Moshe Rosenthal
510(k) history	4 submissions · 4 cleared · 1994-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

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