FDA 510(k) Premarket Notification

K213261 EpilME

CLEARED

Jun 2, 2022
245 days to decision

K213261 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213261/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2021
Decision date	Jun 2, 2022
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Neauvia North America**
Location	Raliegh, NC, US
Contact	Joy Willard
510(k) history	3 submissions · 3 cleared · 2021-2023