FDA 510(k) Premarket Notification

K240537 SMARTXIDE PRO

CLEARED

Mar 20, 2024
23 days to decision

K240537 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 26, 2024
Decision date	Mar 20, 2024
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**El.En S.P.A.**
Location	Hopkinton, MA, US
Contact	Paolo Peruzzi
510(k) history	15 submissions · 15 cleared · 2014-2026