FDA 510(k) Premarket Notification

CLEARED

K222485 SMARTRION COMBI/Alexandrite & Long Pulsed Nd:YAG Laser

Mar 29, 2023
224 days to decision

K222485 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 17, 2022
Decision date	Mar 29, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Ids, Limited**
Location	Gyeonggi-Do, KR
Contact	K.Y. Ahn
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Braunsolutions Regulatory Group**
Contact	Alexander Braun Henderson

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