

K222485 SMARTRION COMBI/Alexandrite & Long Pulsed Nd:YAG LaserMar 29, 2023
224 days to decisionK222485 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026