FDA 510(k) Premarket Notification

K202288 Finebeam

CLEARED

Nov 19, 2021
464 days to decision

K202288 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 12, 2020
Decision date	Nov 19, 2021
Days to decision	464 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Snj Co., Ltd.**
Location	Seoul, KR
Contact	Hyang-Kee Lee
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Med.Com**
Contact	Jongrak Kim

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