

K202288 FinebeamNov 19, 2021
464 days to decisionK202288 · Product code: **GEX** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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