FDA 510(k) Premarket Notification

K213557 Finexel

CLEARED

Apr 12, 2022
155 days to decision

K213557 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2021
Decision date	Apr 12, 2022
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Bio-Med USA, Inc.**
Contact	Chi Young

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