FDA 510(k) Premarket Notification

K223727 Lavieen

CLEARED

Aug 25, 2023
255 days to decision

K223727 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223727/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2022
Decision date	Aug 25, 2023
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wontech Co., Ltd.**
Location	Daejeon, KR
Contact	Hyun Sik Yoon
510(k) history	28 submissions · 28 cleared · 2017-2025