FDA 510(k) Premarket Notification

K211637 AROMA GRAND

CLEARED

Sep 3, 2021
99 days to decision

K211637 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211637/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 27, 2021
Decision date	Sep 3, 2021
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Daeju Meditech Engineering Co., Ltd.**
Location	Seoul, KR
Contact	Seongun Kim
510(k) history	3 submissions · 3 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Withus Group, Inc.**
Contact	April Lee

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