FDA 510(k) Premarket Notification

K213250 Secret Duo

CLEARED

Jun 24, 2022
267 days to decision

K213250 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2021
Decision date	Jun 24, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Ilooda Co,., Ltd.**
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Moon Mason
510(k) history	16 submissions · 16 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Kathy Maynor Consulting**
Contact	Kathy Maynor

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213250/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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