FDA 510(k) Premarket Notification

K202043 Secret Duo

CLEARED

Apr 23, 2021
274 days to decision

K202043 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 23, 2020
Decision date	Apr 23, 2021
Days to decision	274 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	Kevin Walls
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