FDA 510(k) Premarket Notification

K241699 SUPER VELOCE

CLEARED

Aug 13, 2024
61 days to decision

K241699 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241699/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 13, 2024
Decision date	Aug 13, 2024
Days to decision	61 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	Ha Yunjung
510(k) history	16 submissions · 16 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Bt Solutions, Inc.**
Contact	Kim Do Hyun

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