

K241699 SUPER VELOCEAug 13, 2024
61 days to decisionK241699 · Product code: **GEX** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241699/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026