FDA 510(k) Premarket Notification

K231791 PENTO Nd:YAG and Alexandrite laser system

CLEARED

Sep 15, 2023
87 days to decision

K231791 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 20, 2023
Decision date	Sep 15, 2023
Days to decision	87 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	Mason Moon
510(k) history	16 submissions · 16 cleared · 2015-2024

REGULATORY CONSULTANT

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

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/k231791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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