FDA 510(k) Premarket Notification

K230340 Lucas Plus

CLEARED

May 4, 2023
86 days to decision

K230340 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230340/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 7, 2023
Decision date	May 4, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Amt Engineering Co., Ltd.**
Location	Gyeonggi Do, KR
Contact	SeoungSoo Choi
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Bio-Med USA, Inc.**
Contact	Young Chi

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