

K251727 GLAM LED Facial Mask (TB-2386F)Aug 29, 2025
85 days to decisionK251727 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 5, 2025
Decision date	Aug 29, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Shidong Qin
510(k) history	3 submissions · 3 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Contact	Owen He

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

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