

K250261 Heager Medical Laser Family (Sabrina/Adolf)Aug 26, 2025
209 days to decisionK250261 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 29, 2025
Decision date	Aug 26, 2025
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heager GmbH
Location	Haan, DE
Contact	Wolfgang Christiani
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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