

K223685 SmoothCool HR SystemJan 4, 2023
26 days to decisionK223685 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 9, 2022
Decision date	Jan 4, 2023
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jeisys Medical, Inc.
Location	Littleton, CO, US
Contact	Sang Hoon Hwang
510(k) history	15 submissions · 15 cleared · 2008-2024

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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