

K213484 SmoothCool HR SystemApr 20, 2022
173 days to decisionK213484 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 29, 2021
Decision date	Apr 20, 2022
Days to decision	173 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213484/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026