

K253123 CuRAS hybridNov 20, 2025
56 days to decisionK253123 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2025
Decision date	Nov 20, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Classys, Inc.
Location	Seoul, KR
Contact	Judy Seung-yeon Cho
510(k) history	3 submissions · 3 cleared · 2023-2025

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