

**K200693 K2 MOBILE**Nov 19, 2020  
248 days to decisionK200693 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k200693/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 16, 2020
Decision date	Nov 19, 2020
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hulaser, Inc.</b>
Location	Seoul, KR
Contact	InBae Park
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>KMC, Inc.</b>
Contact	DongHa Lee

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200693/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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