

**K213554 Sentient Manufacturing Laser Fiber**Feb 2, 2022  
86 days to decisionK213554 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213554/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2021
Decision date	Feb 2, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sentient Manufacturing , LLC</b>
Location	Park City, UT, US
Contact	Jim Mousseau
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Morningstar Consulting Group, LLC</b>
Contact	Kevin Morningstar

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/k213554/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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