FDA 510(k) Premarket Notification

K213554 Sentient Manufacturing Laser Fiber

CLEARED

Feb 2, 2022
86 days to decision

K213554 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213554/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Morningstar Consulting Group, LLC**
Contact	Kevin Morningstar

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