February 2, 2022

Sentient Manufacturing LLC
℅ Kevin Morningstar
Senior Consultant
Morningstar Consulting Group LLC
20319 E Costilla Ave
Centennial, Colorado 80016

Re: K213554
Trade/Device Name: Sentient Manufacturing Laser Fiber System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 29, 2021
Received: November 8, 2021

Dear Kevin Morningstar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213554

Device Name

Sentient Manufacturing Laser Fiber System

Indications for Use *(Describe)*

The Sentient Manufacturing Laser Fiber System is intended to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelength between 500nm - 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Sentient Laser Fiber 510(k) Summary

I. SUBMITTER:

Jim Mousseau, President/COO
Sentient Manufacturing, LLC
4383 N Forestdale Drive
Park City, UT 84098, USA
j.mousseau@sentientlasers.com

Contact Person:
Kevin Morningstar, Regulatory Consultant (510k Preparer and FDA correspondent)
Morningstar Consulting Group LLC
20319 E Costilla Ave
Centennial, CO 80016
(720) 940-8271
kevin.morningstar@gmail.com

Date Prepared: 26 January 2022

II. DEVICE
Name of Device: Sentient Manufacturing Laser Fiber System
Common or Usual Name: Laser Fiber Optical Delivery System
Classification Name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR Part 878.4810
Regulatory Class: Class II
Product Code: GEX

III. PREDICATE DEVICE
K200234 Quanta System Surgical Laser Fibers
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Sentient Manufacturing Laser Fiber System is a fiber optic delivery device, with the intended use of delivering laser radiation to soft tissue via contact and non-contact procedures, with any compatible laser system.

The Sentient Manufacturing Laser Fibers consist of a fiber optic core, cladding, coating, laser specific compatible connector (proximal end), and optional tip configurations on the distal end (sometimes left bare). The device length can vary from 3 – 5 meters in length with core diameter sizes of 200, 400, 605, 800 and 1000 microns. The device also includes a fiber stripper, fiber cleaver, canula and hand piece to prepare and use the fibers in specific procedures.

The proximal end of the fiber optic is connected to the laser system via SMA-905 or compatible connector type. This connection between the fiber and the laser system allows for the laser radiation to transmit through the fiber core and output at the distal end of the fiber optic. The

fiber connector also keeps the laser centered on the fiber optic surface to ensure proper power transmission throughout the fiber optic.

The fiber optic itself is multilayer; comprised of a core, cladding, and a coating. The fiber cladding and coating provide a protective layer around the core. They also have a low refractive index to keep the power confined inside of the fiber core.

The distal end of the laser fiber can have multiple configurations to fit the needs of the treatment application. The most common configuration of the distal end is primarily a bare fiber, with a polished surface.

V. INDICATIONS FOR USE

The Sentient Manufacturing Laser Fiber System is intended to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelength between 500nm - 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	K200234 Quanta System Surgical Laser Fibers (Predicate)	**Sentient Manufacturing Laser Fiber (New)**	**Comparison**
Trade/Proprietary Name	Quanta System Surgical Laser Fibers	Sentient Manufacturing Laser Fiber	Similar
Generic/Common Name	Laser Fiber Optical Delivery System	Laser Fiber Optical Delivery System	Identical
Classification Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Identical
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Identical
Regulatory Class	II	II	Identical
Product Code	GEX	GEX	Identical
Regulation Number	21 CFR Part 878.4810	21 CFR Part 878.4810	Identical
Review Panel	General & Plastic Surgery	General & Plastic Surgery	Identical
Indications for use	Surgical Laser fibers are intended to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelengths between 500nm – 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.	The Sentient Manufacturing Laser Fiber is intended to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelength between 500nm - 2200nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.	Identical
Operating Wavelength	500-2200 nm	500-2200 nm	Identical

	K200234 Quanta System Surgical Laser Fibers (Predicate)	Sentient Manufacturing Laser Fiber (New)	Comparison
Diameter of Core (microns)	200-1000	200, 400, 605, 800, 1000	Similar
Length	3m or 5m	3 to 5 m	Identical
Connector Type	SMA 905	SMA 905	Identical
Construction Materials	Standard Silica Core Fluoropolymer or Silica Cladding Acrylate, Teflon, Nylon, or Polyimide Buffer	Standard Silica Core Silica Cladding Polyimide (ETFE) Buffer	Similar
Patient Contacting Materials	ETFE or Nylon	Polyimide (ETFE) 304 Stainless	Similar
Provided Sterile	Yes (EtO)	No	Different
Number of Uses	Single Use or Reusable 10x	Single Use or Reusable 10x	Identical

VII. PERFORMANCE DATA

The Sentient Manufacturing Laser Fiber has successfully passed our Internal Performance Testing Parameters. Realtime testing was completed by using side by side comparisons of the predicate device listed. The performance is nearly identical with the predicate device.

The Performance testing included power output percentage, long duration power stability, tensile strength testing, beam profile check, and durability tests.

Power stability testing was completed using a Deka Smartlipo 18W Nd:YAG laser, which is a compatible and FDA cleared laser system. Testing was done on the same laser system to ensure stability control. 10 individual power stability tests were done on the Predicate Device (K200234) and the Sentient Manufacturing Laser Fibers to provide a direct data comparison. A Power Fluctuation percentage was calculated. The power stability tests involved performing a mock clinical treatment with the typical duration of 30 minutes. The Smartlipo laser was pulsing at the maximum power of 18 watts and continuously monitored by an external laser energy power meter. A power sample was then taken every 3 minutes to provide 10 data points. After each power stability test, we performed an industry standard sterilization cycle through the autoclave and re-ran the power test 10 times. This was done to mimic the maximum life expectancy of the Sentient Manufacturing Laser Fibers.

Tensile strength testing was performed by analyzing the maximum bend radius of both the Predicate Device (K200234) and the Sentient Manufacturing Laser Fiber. Each fiber had 2 feet of length mounted to a folding bracket and was collapsed until the fiber core broke. Data was collected by looking at degree of bend. We discovered that each device had very similar results in the maximum bend radius due in part to having similar composition of fiber core, cladding, and coating.

The beam profile of both fibers was analyzed using a 1,064 nm Nd:YAG Deka Smartlipo laser. The 1,064 nm laser emits a Near Infrared beam that is focused and fired at the proximal end of the laser fibers. This laser then transmits through the fiber core and emits out of the distal end. The distal end of the fiber was then pointed at a ceramic disk so it could be analyzed using an Infrared camera. Beam consistency and mode of the Sentient Manufacturing Laser Fibers were then visually compared to the predicate device and showed them to be as expected virtually identical.

Durability tests were performed on both the both the Predicate Device (K200234) and the Sentient Manufacturing Laser Fibers. These tests include heat testing and sterilization durability. Both fibers were placed into the fiber oven for a 12-hour duration at 150 degrees C and inspected for defects. Our sterilization inspection was completed by running each fiber optic assembly through 20 autoclave cycles and inspected for defects of which none of note were detected.

VIII. CONCLUSION

The non-clinical data support the safety of the device, and design verification and validation demonstrate that the Sentient Manufacturing Laser Fiber System performs as intended in the specified use conditions. The Sentient Manufacturing Laser Fiber System does not raise new types of questions regarding safety or effectiveness and is considered to be substantially equivalent to the legally marketed predicate device (K200234).