October 3, 2022

Nanospectra Biosciences, Inc.
% Shepard Bentley
Consultant
Bentley Biomedical Consulting, LLC.
28241 Crown Valley Parkway
Suite 510(K)
Laguna Niguel, California 92677

Re: K202953
Trade/Device Name: Aurolase Therapy, Laser Delivery Device (LDD)
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: August 31, 2022
Received: August 31, 2022

Dear Shepard Bentley:

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,

Jianting Wang
Acting 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*)
K202953

Device Name
Aurolase Therapy Laser Delivery Device

Indications for Use (*Describe*)

The Aurolase Therapy, Laser Delivery Device is a fiber-optical laser delivery device to be used with a compatible 810nm laser device for laser-based applications and procedures that are cleared for the compatible laser.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW

The burden time for this collection of information is estimated to average 79 hours per response, including the Time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency many not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K202953

Sponsor: Nanospectra Biosciences Inc.
Address: 8285 El Rio St # 150, Houston, TX 77054
Phone Number: (713) 842-2720
Email address: info@nanospectra.com

Contact Person: Shepard G. Bentley

Trade name: Aurolase Therapy, Laser Delivery Device (LDD)
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Regulation: 21 CFR 878.4810

Predicate Device: Visualase Cooled Laser Application System, Laser Diffusing Fiber, Cooling Catheter System, Bare Tip Fiber (K053087)

Description of Device:

Laser light generated by the Laser Module is delivered to a Laser Delivery Device (LDD) Assembly, that is comprised of three components: the Laser Catheter Assembly (LCA), the Optical Fiber Diffuser (OFD), and the Coolant Supply Set (CSS). The LCA and OFD transmit laser energy to the tissue situated at their distal regions, to achieve the desired effect of the intended use. The use of coolant provides cooling for the surfaces of the CSS in contact with both the tissue and the LCA.

Indications for Use:

The Aurolase Therapy, Laser Delivery Device is a fiber-optical laser delivery device to be used with a compatible 810nm laser device for laser-based applications and procedures that are cleared for the compatible laser.

Technological Characteristics:

- A transparent, dual lumen Laser Catheter Assembly (LCA) for percutaneous delivery of the optical fiber into, or adjacent to, the target tissue and to provide a means for actively cooling tissue immediately adjacent to the LCA.
- A Coolant Supply Set (CSS) that provides the source of cooling liquid to the LCA. The tubing set is terminated in a standard spike and consists of a length of tubing to permit the placement of a peristaltic pump anywhere along its length and the coolant recovery bag for collecting the cooling liquid after a single transit of the LCA.
- A glass/silica Optical Fiber Diffuser (OFD) assembly for delivering near infrared light to the target tissue. The optical fiber is terminated in an 18mm long diffuser that emits light radially from the fiber.

Shelf Life:

The shelf life of the Aurolase Therapy Laser Delivery Device is six months from the date of sterilization.

Supporting Technology:

The Nanospectra Biosciences Aurolase Therapy Laser Delivery Device (LDD) may be used with any appropriate commercially available introducer (e.g., Terumo® Surflo® I.V. Catheter 14G x 2", cleared under K133280), and should be used with the compatible laser system; LightForce® LTS Model 2500 cleared under K173067, and Langer Instruments BT100-1L peristaltic pump.

Comparison with the predicate device:

Technological Characteristic	**Subject Device Aurolase Therapy LDD**	**Predicate Device VCLAS**	**Comparison**
Product Code	GEX	GEX	Same
Regulation	21 CFR §878.4810	21 CFR §878.4810	Same
Classification	2	2	Same
Device Type	Accessory to powered surgical laser instrument	Accessory to powered surgical laser instrument	Same
Composition	Three-part system for delivering laser energy	Three-part system for delivering laser energy	Same
Biocompatible per ISO 10993-1	Biocompatible materials	Biocompatible materials	Same
Mode of Action	Delivery of laser energy to achieve the desired effect of the intended use	Delivery of laser energy to achieve the desired effect of the intended use	Same
Compatible output power	Up to 5 W	Not disclosed	
Compatible wavelength(s)	810nm, +/- 10nm	800nm – 1064nm	Similar
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Number of Uses	Single Use, disposable	Single Use, disposable	Same

Non-Clinical Performance Data:

The results of testing, including rigorous physical and environmental use studies, sterility, and biocompatibility tests, support a conclusion that the Aurolase Therapy LDD satisfies the requirements of performance to achieve its intended effect within its indication for use, and have not produced any additional risks of hazard leading to harm of the user and/or the patient within its intended use.

Conclusion:

On the basis of the comparison with the predicate device and on the non-clinical performance data, we conclude that Aurolase Therapy, Laser Delivery Device (LDD) does not introduce any new questions of safety or effectiveness, and is substantially equivalent to the predicate.

End of 510(k) Summary