July 2, 2025

Nanospectra Biosciences, Inc.
% Shepard Bentley
Principal Consultant
Bentley Biomedical Consulting, LLC
29461 Troon Street
Laguna Niguel, California 92677

Re: K243701
Trade/Device Name: AuroLase® 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: June 2, 2025
Received: June 2, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.07.02 19:47:12 -04'00'

Tanisha Hithe
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)*
K243701

Device Name
AuroLase System

Indications for Use *(Describe)*
The AuroLase System is intended for use in delivering up to 9 Watts of continuous wave radiation to a flexible optical fiber for use in ablation, incision, excision, coagulation and vaporization of soft tissues in open and endoscopic surgical procedures including in general surgery, ophthalmology/oculoplastic, urology, gastroenterology, gynecology, otorhinolaryngology, pulmonary/thoracic, dermatology/plastic surgery, neurosurgery (coagulation only), and orthopedic.

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.

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
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PRAStaff@fda.hhs.gov

"An agency may 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

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K243701

1. Date of Preparation
   07/01/2025

2. Applicant

Name:	Nanospectra Biosciences, Inc.
Address:	8285 El Rio Street, Suite 150, Houston, Texas 77054
Contact Person:	David Jorden, CEO
Telephone:	713.842.2720
FAX:	713.440.9349
Email:	david.jorden@nanospectra.com

3. Identification of the Proposed Device

Trade/Device Name:	AuroLase System
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Powered Laser Surgical Instrument
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

4. Identification of Predicate Device

510(k) Number:	K051996
Product Name:	Diomed Delta 15
Manufacturer:	Diomed, Ltd.

5. Device Description

The AuroLase® System (AS) is a portable, cart-based integrated liquid cooled laser system for use in professional healthcare facilities. The AuroLase System is used to generate photothermal ablation of selected soft tissues using 1-9W of near infrared optical power via 1 or 2 optical fibers either individually or simultaneously while providing liquid coolant to moderate the temperature at the fiber surface. The laser is delivered to the tissue of interest via an optical fiber system, the Nanospectra Laser Delivery Device (LDD), cleared via K202953. It is for prescription use only.

Central to the AuroLase System is the AuroLase Laser Device (ALD), a dual channel, continuous-wave, class IV GaAs diode laser (**Figure 1** - red section) that provides the optical energy used to excite to soft tissues to ablative temperatures. The ALD incorporates an integrating sphere power meter (optometer) which is used to adjust the laser output that is delivered to the patient to the power shown on the display. Enabling the ALD's functionality is the AuroLase Control Unit (**Figure 1** - green section) which incorporates: a) a peristaltic pump for providing sterile coolant to the Laser Delivery Devices, b) dual ultrasonic sensors to assure that coolant flows through the LDDs, c) a footswitch to control laser activation, d) temperature monitors for up to two optional external thermocouples, and e) a software application that controls, integrates, and monitors these functions. A medical-grade power supply is near the base of the unit to provide electrical service to the rest of the system as well as mechanical stability.

The AS is designed and tested for operation in a professional healthcare facility.

AuroLase System Incorporates:

AuroLase Laser Device (ALD)

- The ALD is a dual-channel 810nm laser system capable of 1-9W of output power per channel, adjustable in 0.25W increments.
- The optical outputs of the ALD are configured to insert their optical energy into mated SMA-905 terminated optical fibers with diameters of ≥600µm and numerical apertures of ≤ 0.37.
- An integrating sphere optometer head is used to calibrate the laser power extant at the termination of the diffuser-tipped optical fibers.
- Separate laser channel display information, e.g., channel standby/ready status, power output, and system alerts and alarms.
- A laser ON tone which is either continuous or periodic to distinguish between the two laser

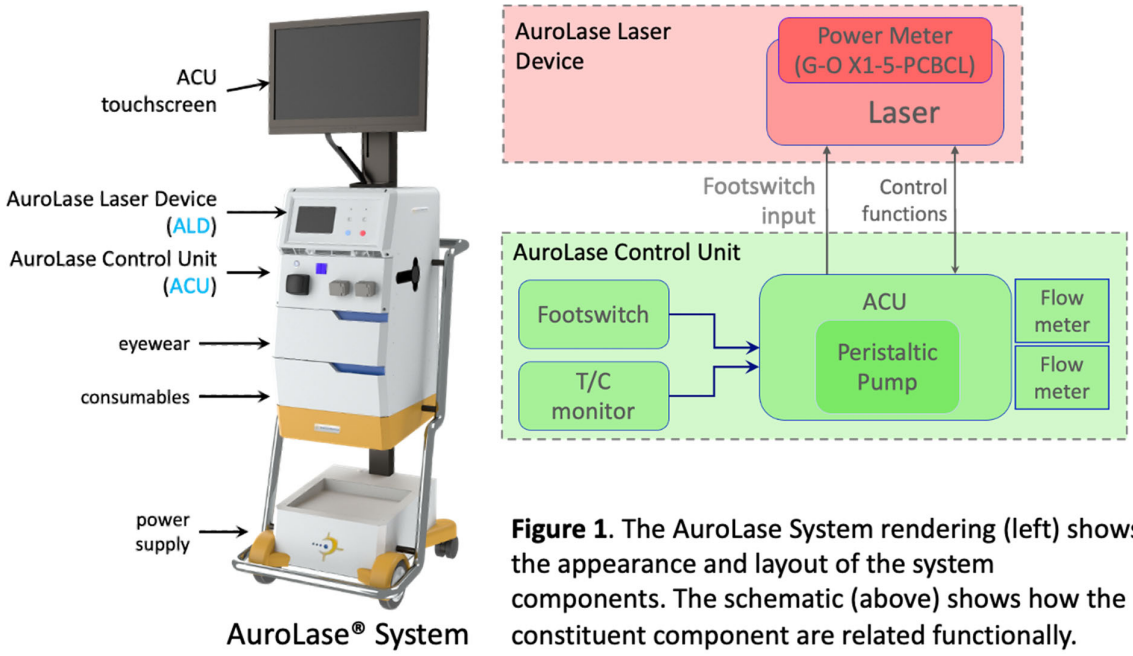

Figure 1. The AuroLase System rendering (left) shows the appearance and layout of the system components. The schematic (above) shows how the constituent component are related functionally.

channels.

- A laser "watchdog" timer in order to allow for re-positioning of the laser catheters without the laser returning to standby mode for up to 10min.

AuroLase Control Unit (ACU)

- Conveys essential information to the OR staff, including:
- separate laser ready status
- coolant flow status
- system warnings and alerts

Fluid Handling Unit

- houses the coolant pump and electronics.
- houses the two coolant flow sensors and electronics.

- houses two thermocouple ports and electronics.

Storage

- The ACU has covered drawers for storing:

- safety eyewear, 8-10 pair

External Mounting Hardware

- A hook for mounting 0.5-3.0L saline or water coolant supply bags.
- A hook for mounting two 1.5L Coolant Recovery Bags.

Laser Actuation Footswitch

- Footswitch actuation is a momentary switch to enable "tap-on/tap-off" operation rather than continuous depression.
- The footswitch simultaneously actuates the laser, coolant pump, and countdown timer.

Medical Grade Power Supply

- Located in base to provide mechanical stability.

6. Indications for Use

Intended Use

The AuroLase System is intended for use in ablation, incision, excision, coagulation and vaporization of soft tissues in open and endoscopic surgical procedures.

Indications for Use

The AuroLase System is intended for use in delivering up to 9 Watts of continuous wave radiation to a flexible optical fiber for use in ablation, incision, excision, coagulation and vaporization of soft tissues in open and endoscopic surgical procedures including in general surgery, ophthalmology/oculoplastic, urology, gastroenterology, gynecology, otorhinolaryngology, pulmonary/thoracic, dermatology/plastic surgery, neurosurgery (coagulation only), and orthopedic.

7. Substantially Equivalent (SE) Comparison

Comparison of the Indications for Use: Indications for use statement of the subject and predicate devices are comparable.

Comparison of Technology:

Device & Predicate Device(s):	K243701	K051996
General Device Characteristics		
Laser Source	Diode	Diode
Wavelength (nm)	810±10	810±20
Power (W)	1.0-9.0 W/fiber Up to 18 W total	≤ 15
Pulse width (s)	NA (CW)	0.1-CW
Repetition Rate (s)	NA (CW)	0.1-CW
Length of the laser irradiating part of the applicator (mm)	10/20/30 (isotropic)	10 mm or end firing
Fiber Cooled	Yes	No
Coolant	Saline	NA
Flow Rate	0 or 12 mL/min/channel 0 or 24 mL/min for two channels	NA
No. of deployable fibers	1 or 2 (see below)	1
Aiming Beam	650 nm	650 nm

The technological features of the subject device are comparable to the corresponding technological

features of the predicate device. Any difference in the technological features do not raise different questions of safety and effectiveness.

8. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility;
- Software Validation & Verification Test;
- Bench Testing to verify the performance.

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.