November 28, 2025

Dendrite Imaging, Inc.
℅ Terese Bogucki
Senior Consultant
Decus Biomedical Inc.
2342 Shattuck Ave
Ste #333
Berkeley, California 94704

Re: K253303
Trade/Device Name: Dendrite Imaging System
Regulation Number: 21 CFR 878.4550
Regulation Name: Autofluorescence Detection Device For General Surgery And Dermatological Use
Regulatory Class: Class II
Product Code: QDG
Dated: September 29, 2025
Received: September 29, 2025

Dear Terese Bogucki:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.11.28 12:29:47 -05'00'

for 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)*
K253303

Device Name
Dendrite Imaging System

Indications for Use *(Describe)*
The Dendrite Imaging System is indicated for use in real-time capturing and viewing of autofluorescent images of nerves and can be used as an adjunctive method to assist in the location of nerves during surgery. Use of the device is intended to assist, not replace, experienced visual assessment. The system is not to be used to confirm the absence of nerve tissue and is only to be used to assist in locating visually identified nerves.

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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510(K) SUMMARY

510(k) #: K253303

Date Preparation: November 28, 2025

Contact Details:
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Correspondent Contact: Ms. Terese Bogucki
Correspondent Contact Email: terri@decusbiomedical.com

Device Name:

Device Trade Name: Dendrite Imaging System

Common Name: Autofluorescence detection device for general surgery and dermatological use

Classification Name: Parathyroid Autofluorescence Imaging Device

Regulation Number: 878.4550

Product Code(s): QDG

Legally Marketed Predicate Devices:

Predicate #: K190891

Predicate Trade Name (Primary Predicate is listed first): Fluobeam LX

Product Code(s): QDG

Device Description Summary:

The Dendrite Imaging System provides real-time near ultraviolet (NUV) fluorescence imaging of nerve tissue. The device is indicated for use during open surgical procedures as an adjunctive method to assist in the location of nerves due to the autofluorescence of this tissue. Use of the Dendrite Imaging System is intended to assist, not replace, experienced visual assessment per the

standard of care. The device is not to be used to confirm the absence of nerve tissue and is only to be used to assist in locating visually identified nerves.

The Dendrite Imaging System enables surgeons to observe fluorescent images of nerve tissue thanks to the natural autofluorescence of this tissue when exposed to NUV light. The system consists of a handheld camera head linked by a custom cable to the control display. The camera head contains a CMOS video camera and white and NUV light-emitting diodes (LEDs). The NUV LED is used to excite the nerve and a camera inside the camera head captures the fluorescent image for display on the touchscreen monitor. The white LED is used to illuminate the surgical field and in the generation of an "overlay" view of the nerve autofluorescence with the surrounding area. The control display is an off-the-shelf integrated computer/touchscreen display that receives the digital video signals from the camera head and displays them. Adjustments to the LEDs and camera can be made through the user interface on the control display. The surgeon may also save images or video during camera use for later export to a USB.

Intended Use/Indications for Use:

The Dendrite Imaging System is indicated for use in real-time capturing and viewing of autofluorescent images of nerves and can be used as an adjunctive method to assist in the location of nerves during surgery. Use of the device is intended to assist, not replace, experienced visual assessment. The system is not to be used to confirm the absence of nerve tissue and is only to be used to assist in locating visually identified nerves.

Indications for Use Comparison:

The indications for use are different in that the subject device images nerve tissue while the predicate images the parathyroid gland. This does not constitute a new intended use as both devices are used in the same way to generate autofluorescence to detect tissues or structures. Both devices are intended for general surgery use as an adjunct tool, and neither device is intended to provide a diagnosis.

Technological Comparison:

Comparator	Dendrite Imaging System	Fluobeam LX (K190891)	Equivalence Comparison
Fundamental scientific technology	Emits LED light at 385 nm to generate fluorescent light around 450 nm	Emits Class 1 laser light at a wavelength of 750 nm to generate fluorescent light in the range of 800-900 nm	The subject device uses LED light at near ultraviolet wavelengths in contrast with the predicate that uses laser light at near infrared wavelengths. No safety questions are raised as light safety is confirmed by bench testing following consensus standards. The imaging systems are designed to detect the specific wavelengths of light emitted that are representative of the different tissues being imaged. No effectiveness questions

Comparator	Dendrite Imaging System	Fluobeam LX (K190891)	Equivalence Comparison
			are raised as testing demonstrates device performance.
Components	Handheld camera unit Ethernet cable Control display (integrated computer/ touchscreen display) Power cable	Handheld camera unit Control box Control box cable Touchscreen display (integrated computer/display) Power cable	Similar – the subject device is controlled by only the computer while the predicate requires a separate control box. The cable on the subject device is detachable while in the predicate it is part of the camera unit.
Operating Modes	Fluorescence imaging	Fluorescence imaging	Same
Light Sources	One NUV LED One white light LED	Two lasers Two near infrared LEDs Six white light LEDs	The predicate has more light sources as it has multiple intended uses. While the LED light sources are on the camera head, the control box generates the laser light, which is transmitted to the camera head through a fiber optic connection. The subject device is simpler and only has LED light sources at the camera head.
Camera Technology	Monochromatic CMOS sensor	CCD sensor	Similar – subject device uses newer camera sensor technology than the earlier predicate
Light Output Energy	<1 W	Laser power density: 5.0 ± 0.5 mW/cm² at 20cm	Differences are due to the subject device using an LED instead of laser light to illuminate the surgical field
White LED Wavelength	Broadband LED with normal illumination 400< λ <700 nm	Broadband LEDs with normal illumination λ<800 nm	Similar – both devices use LEDs to generate white light of similar wavelengths. The predicate device has multiple white LEDs while the subject device has one.
Contrast Agent	None	None (for parathyroid imaging)	Same
Working Distance	30-34 cm	20-30 cm	The subject device working distance is based on the default focus of the camera and enables the camera to be positioned further away from the surgical field than the predicate. The

Comparator	Dendrite Imaging System	Fluobeam LX (K190891)	Equivalence Comparison
			predicate device has an autofocus feature so it can be positioned at a larger range of distances than the subject device.
Focal Plane Depth	4 cm	2-3 cm	Similar
Resolution (focal plane)	150µm	300 µm to 50 µm depending on magnification	Subject device resolution is within the range of the predicate. Animal and clinical testing demonstrate the resolution is appropriate for the intended use.
Field of View	18 cm x 15 cm (at 32 cm distance)	20 cm x 14 cm (at 30 cm distance)	Similar – the differences in the illuminated field sizes are not significant. The predicate device, with 10x zoom could have a field of view as small as 2.2 cm x l.5 cm.
Magnification	Digital zoom (2x and 4x)	10x zoom	Similar – both devices offer options for magnifying the images
Maximum Frame Rate	14 frames/sec	25 frames/sec	While the subject device has a lower frame rate, animal and clinical testing demonstrate it is acceptable for its intended use. It can also be noted that the subject device is not used in a situation where there is much movement.
Camera Bit Depth	8 bits	8 bits	Same
Image Size (pixels)	1224 x 1024	696 x 576	Subject device video/images have more pixels than the predicate
Image Format	JPEG	PNG	Similar – both devices export widely used image formats
Video Format	MPEG	MP4	Similar – both devices export widely used video formats
Measurement Functionality	None	None	Same
Computer Power Supply	Wall (for control display)	Wall (to control box and to PC)	Same
Camera Head Power Supply	Power over Ethernet (cable to control display)	Cable to control box	Same

Comparator	Dendrite Imaging System	Fluobeam LX (K190891)	Equivalence Comparison
Image Display	Remote display (no display on camera)	Remote display (no display on camera)	Same
Patient Contacting Materials	Non-patient contacting device	Non-patient contacting device	Same – the devices are positioned away from and do not contact the patient
Sterility	Non-sterile, used with cleared sterile sleeve when placed in the sterile field during surgical procedures	Non-sterile, used with off-the-shelf sterile sleeve when placed in the sterile field during surgical procedures	Same – both devices are covered by a sterile sleeve to maintain the sterile field during surgery
Bench Testing	Field size Focal range LED intensity	Homogeneity of the excitation illumination pattern Live image quality (spatial resolution and acquisition frame rate) Fluorescence sensitivity	Different tests reflect the different technology (laser vs LED) and application (detection limit of ICG fluorescence) of the two devices
MR Compatibility	Not compatible	Not compatible	Same
Testing Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 62471 ISTA-3A	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 62471	Similar – both devices comply with electrical safety and electromagnetic compatibility standards. Because the subject device uses LEDs and not laser light, IEC 60825-1 does not apply. The subject device also underwent conditioning and shipping simulation per the recognized standard.

Both the subject and predicate devices have the same tissue autofluorescence principle of operation, in which light of a specific wavelength is emitted from the device to trigger light emission by tissue and that light is detected by a camera. Differences in technological characteristics include the light source used for tissue excitation. While the predicate device uses a 750 nm wavelength laser, the subject device uses a non-coherent light-emitting diode at 385 nm. The optics and cameras used to capture the autofluorescence also have slightly different characteristics. The differences in light source, wavelength, and camera specifications do not

raise different questions of safety or effectiveness as the non-clinical and in vivo testing establish that the Dendrite Imaging System device is at least as safe and effective as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

Non-clinical testing was completed to confirm that the Dendrite Imaging System is substantially equivalent to the predicate imaging system and that the differences in technological characteristics do not raise any new issues of safety or effectiveness.

Comprehensive testing of the device, including functional verification, electrical safety, electromagnetic compatibility (EMC), light safety, software and system verification, cybersecurity testing, and animal testing, demonstrate that the design output meets the design input requirements and intended use.

EMC and Electrical Safety Testing

Electrical Safety and Electromagnetic Compatibility testing was conducted to demonstrate compliance with IEC60601-1 (2020-08), IEC60601-1-6 (2020-07), IEC60601-1-2 (2020), and IEC TS 60601-4-2 (2024-03).

Light Safety Testing

Light safety testing conducted in compliance with IEC 62471(2006) demonstrates the white and near ultraviolet light used in the camera is safe.

Packaging Validation

Packaging validation confirms the device operates as intended after conditioning and shipping simulation performed in compliance with ISTA-3A (2018).

Software Verification

Software verification testing demonstrates that the device meets design specifications. Software documentation has been provided according to FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (June 2023). The Software Lifecycle Process aligns with the principles of IEC 62304 (2016).

Cybersecurity Testing

Vulnerability and penetration testing were conducted according to FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (June 2025).

System Verification

System verification testing verifies that the device overall functionality meets the design specifications.

Animal Testing

Animal testing performed in compliance with applicable requirements in the GLP regulation (21 CFR Part 58) demonstrates the Dendrite Imaging System performance and safety when imaging nerves in guinea pigs. Testing resulted in a 95% confidence interval for nerve sensitivity and positive predictive value of 100% (the system produces autofluorescence in nerve tissue) with no device-related adverse events.

Clinical Testing Summary

An observational clinical study was conducted with the goal of collecting example images to demonstrate that the device can detect autofluorescent signals of nerves consistent with the indications for use and that clinical confounders do not impact device use. Twenty-three subjects undergoing open surgery were enrolled in the study. The images collected from these cases provide 38 unique nerve autofluorescence images of 49 nerves representing 24 different nerve types. The study demonstrates that regardless of patient or anatomic region, nerve tissue can be reliably imaged using the device. No adverse events occurred during use of the subject device.

Conclusions

Based on the intended use, technological characteristics, and performance testing, the Dendrite Imaging System is substantially equivalent to the predicate device. This determination is based on nonclinical testing demonstrating that the system meets state of the art standards for electrical and thermal safety, electromagnetic compatibility, light safety, cybersecurity, and packaging integrity. The bench testing verified that the design specifications and customer requirements have been met. Animal and clinical testing demonstrated the subject device can be used safely and effectively according to its intended use with no new risks identified. Animal testing confirmed that the autofluorescence signals produced by the system are nerve tissue. Clinical testing demonstrates that the device can be used to image nerve tissue in a range of patients and anatomic regions. These activities demonstrate that the minor technological differences between the Dendrite Imaging System and its predicate device do not raise different issues of safety or effectiveness and that the subject device performs at least as well as the legally marketed predicate.