October 7, 2025

DAMAE Medical
% Rory Carrillo
Regulatory Consultant & US Agent
Cosm
45 Bartlett St.
San Francisco, California 94110

Re: K252851
Trade/Device Name: deepLive (OSP12 + DMS)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: September 8, 2025
Received: September 8, 2025

Dear Rory Carrillo:

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,

Jessica Carr -S

Jessica Carr, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252851

Please provide the device trade name(s).

deepLive (OSP12 + DMS)

Please provide your Indications for Use below.

deepLive is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing three-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.

Please select the types of uses (select one or both, as applicable).

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

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510(k) Summary

General Information

510(k) Sponsor	DAMAE Medical
Address	14 Rue Sthrau Paris, France 75013
Correspondence Person	Rory A. Carrillo Regulatory Consultant & U.S. Agent
Contact Information	Email: rory@cosmhq.com Phone: 415-255-5516
Date Prepared	September 08, 2025

Proposed Device

Proprietary Name	deepLive
Common Name	n/a
Classification Name	Radiology
Regulation Number	21 CFR 892.1560
Regulation Name	Ultrasonic Pulsed Echo Imaging System
Product Code	NQQ
Regulatory Class	II

Predicate Device

Proprietary Name	deepLive
Premarket Notification	K240610
Classification Name	Radiology
Regulation Number	21 CFR 892.1560
Regulation Name	Ultrasonic Pulsed Echo Imaging System
Product Code	NQQ
Regulatory Class	II

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Device Description

The deepLive device is an update to the previously cleared deepLive device (K240610). The update includes the addition of a hand-held Dermoscope (DMS).

deepLive was designed for an easy integration into clinical practices. The device is composed of:

- **A mobile cart,** allowing the user to move the whole device and including a cart tablet for accessories.
- **A touchscreen**, fixed on the cart mast, displaying the software interfaces to the user.
- **A first hand-held probe (LC-OCT),** integrating the LC-OCT imaging system (interferometric microscope, OCT camera). The probe is connected to the CPU front panel by a sheathed cable bundle, and stored in a dedicated probe-holder fixed on the cart tablet.
- **A second hand-held probe (DMS)**, complementary to the LC-OCT, integrating a dermoscope and providing wide-field surface color images. The probe is connected to the CPU by a USB cable, and stored in a dedicated probe-holder fixed on the cart tablet.
- **A central power unit (CPU)**, mounted on the cart, integrating various imaging and electronic peripherals (laser, computer, electronic cards, drivers, power supplies, etc.), driving and powering the imaging probe.
- **A software** running on the device's computer, which controls the components of the system, acquires and processes images, and provides user interfaces for performing examinations and managing data.

deepLive hardware interfaces are located on the front-panel of the CPU. Input/output connections include:

- 1 Display port to connect the screen
- 3 USB ports to connect external drives (Wifi key, hard drive disk, etc.)

deepLive software runs on a computer embedded in the CPU of the device. The computer uses Windows Enterprise LTSC operating system. The software executable and all dynamic libraries needed for program execution are deployed at a specific location in the file system.

The secured access to the computer operating system, deepLive software and data folders are managed by Windows sessions authentication system. The computer hosting deepLive is also likely to have applications installed by DAMAE Medical:

- Synology Drive: used to retrieve device data for maintenance and software improvement purposes.
- TeamViewer: remote control software used for software manual update and software issues solving.

Indications for Use

deepLive is intended to be used as a non-invasive imaging tool in the evaluation of external human tissue microstructure by providing three-dimensional, cross-sectional and en-face real-time depth visualization for assessment by physicians to support in forming a clinical judgment.

Substantial Equivalence

The proposed device, deepLive, is substantially equivalent to the predicate device, deepLive (K240610) and is intended for the same clinical application. No new questions related to safety or effectiveness are raised by the proposed device, thus the proposed device can be considered substantially equivalent to the predicate device.

Verification and Validation Activities

Verification and validation activities included in this submission followed the same testing as the previously cleared deepLive device (K240610), with the addition of test cases to address the addition of a hand-held dermoscope probe.

All V&V test cases passed the predetermined acceptance criteria. Results of V&V testing are adequate to support substantial equivalence of the deepLive device included in this submission to the previously cleared deepLive device (K240610).

Conclusion

Based on the information submitted in this Special 510(k) submission, and based on the indications for use, technological characteristics and V&V testing, the deepLive device raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.

Technological Characteristics Comparison

Feature/ Function	**Proposed Device** deepLive	**Predicate Device:** deepLive (K240610)	**Substantially Equivalent**
Measurement Technology	Optical Coherence Tomography	Optical Coherence Tomography	Same
Near Infrared Wavelength (700-1400mm)	Yes	Yes	Same
Lite Source Wavelength	800 nm	800 nm	Same
Frame rate (fps)	B-scan: 8 fps A-scan : 8 fps	B-scan: 8 fps A-scan : 8 fps	Same
Lateral resolution	1.3 µm	1.3 µm	Same
Axial resolution	1.1µm	1.1µm	Same
Lateral Scanning Range	1.2 mm	1.2 mm	Same
Axial Scanning Range	0.5 mm	0.5 mm	Same
Optical Safety	Class 1	Class 1	Same
Hand-held probes	LC-OCT probe and optional dermoscope probe	LC-OCT probe	Similar