July 9, 2024

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

Re: K240610
Trade/Device Name: deepLive
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: May 28, 2024
Received: May 28, 2024

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.

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, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240610

Device Name

deepLive

Indications for Use *(Describe)*

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.

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.

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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
Contact Information	Email: rory@cosmhq.com Phone: 415-580-0916
Date Prepared	February 29, 2024

Proposed Device

Proprietary Name	deepLive OSP12
Common Name	deepLive
Classification Name	System, Imaging, Optical Coherence Tomography (Oct)
Regulation Number	21 CFR 892.1560
Regulation Name	Ultrasonic pulsed echo imaging system
Product Code	NQQ
Regulatory Class	II

Predicate Device

Proprietary Name	VivoSight Dx Topical OCT System
Premarket Notification	K153283
Classification Name	System, Imaging, Optical Coherence Tomography (Oct)
Regulation Number	21 CFR 892.1560
Regulation Name	Ultrasonic pulsed echo imaging system
Product Code	NQQ
Regulatory Class	II

Device Description

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

A. A mobile cart, allowing the user to move the whole device and including a cart tablet for accessories.
B. A touchscreen, fixed on the cart mast, displaying the software interfaces to the user.
C. A hand-held probe, 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. The probe is the interface between the device, the doctor and the patient: its measuring head (tip) must be positioned in contact with the patient's skin.
D. 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.
E. 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

Feature/ Function	**Proposed Device** deepLive	**Predicate Device:** *VivoSight Dx* (K153283)	**Substantially Equivalent**
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.	VivoSight Dx is a Multi-Beam Optical Coherence Tomography (OCT) system indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body.	Yes
Measurement Technology	Optical Coherence Tomography	Optical Coherence Tomography	Yes
Near Infrared Wavelength (700-1400mm)	Yes	Yes	Yes
Lite Source Wavelength	800 nm	1305 nm	Yes
Frame rate (fps)	B-scan: 8 fps A-scan : 8 fps	5fps	Yes
Lateral resolution	1.3µm	7.5 µm	Yes
Axial resolution	1.1µm	10 µm	Yes
Lateral Scanning Range	1.2 mm	6 mm	Yes
Axial Scanning Range	0.5mm	1 mm	Yes
Optical Safety	Class 1	Class 1	Yes

Performance Testing

Safety and performance of the deepLive device have been evaluated and verified in accordance with product and software specifications and applicable performance standards through verification, validation, nonclinical performance, and safety testing. Product requirements testing was performed to test the device requirements at the product level. Test cases covered general product functionality, hardware functionality, accuracy of measurement methods, labeling, manufacturability, maintenance, and packaging & environmental conditions.

Software integration testing was performed to test requirements defined in the software specifications documents. These tests covered both the integration of unitary software bricks, as well as the verification of the functional requirements and non-functional constraints of the complete software system. This also includes cybersecurity testing to test that cybersecurity risk control measures are correctly implemented at the product level.

Validation testing was performed to validate the finished product and leveraged several validation tests including user requirements testing, safety testing, usability testing, biological evaluation testing, and nonclinical evaluation. Safety testing was performed in accordance with the following standards:

- IEC 60601-1:2005 - Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances Requirements and tests
- EN 60825-1 :2014 - Safety of laser products - Part 1: Equipment classification and requirements
- EN 62471:2008 - Photobiological Safety of lamps and lamp systems
- ASTM D4169-22 - Distribution cycle 12 (road and air modes) - Assurance level II
- ISO 10993-1:2018 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Verification, validation, nonclinical performance, and safety test results established that the device meets its design requirements and indications for use, that it is as safe and as effective as the predicate device, and that no new questions of safety and effectiveness have been raised.

Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the deepLive device raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.