June 5, 2025

DeepHealth, Inc.
℅ B. Nathan Hunt
Head of Quality, Regulatory, and Compliance
212 Elm Street
SOMERVILLE, MA 02144

Re: K243703
Trade/Device Name: TechLive
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 9, 2025
Received: May 9, 2025

Dear B. Nathan Hunt:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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)*

K243703

Device Name

TechLive

Indications for Use *(Describe)*

TechLive is a software application intended to provide remote access for real-time image acquisition, assistance, review, monitoring and standardization of imaging devices across multiple locations. It is a vendor neutral solution allowing read-only or full access control to connected devices. TechLive is also intended for training of medical personnel working on medical imaging devices. TechLive is not intended for diagnostic use.

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.

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510(k) Summary
DeepHealth, Inc
TechLive

In accordance with 21 CFR 807.92, the following summary of information is provided, on this date, May 28, 2025:

1. 510(k) SUBMITTER

DeepHealth, Inc
212 Elm St.
Somerville, MA 02144
Tel: 443-506-8911

Contact Person:

B. Nathan Hunt
Head of Quality, Regulatory, and Compliance

DeepHealth, Inc.
212 Elm St
Somerville, MA 02144
Tel: 443-506-8911

Date Prepared:

2. May 28, 2025DEVICE

Trade Name of Device:
TechLive

Common or Usual Name:
TechLive

Classification Name:
Medical Image Management And Processing System (21 CFR 892.2050)

Regulation Class: II

Product Code: LLZ

3. PREDICATE DEVICE

Predicate Device:

Trade Name: Syngo Virtual Cockpit

Common or Usual Name:
System, Image Processing, Radiological

Classification Names:
Medical Image Management And Processing System (21 CFR 892.2050)

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Regulation Class: II

Product Code: LLZ

510(K) No.: K232744

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

TechLive is a software application intended to provide remote access for real-time image acquisition, assistance, review, monitoring and standardization of imaging devices across multiple locations. It is a vendor neutral solution allowing read-only or full access control to connected devices. TechLive is also intended for training of medical personnel working on medical imaging devices. TechLive is not intended for diagnostic use.

Clinical users can remotely access imaging devices from a computer via a secure software connection that streams video and audio, including access to keyboard and mouse controls. This setup allows remote users to assist local in-suite assistants or other clinical users by means of audio/video connection or perform remote acquisitions themselves. Depending upon the device used to acquire the images, the remote access can allow for "view mode", to support the in-suite assistant, or "control mode", where the remote user controls the console software of the imaging device. Remote access to the local imaging device can only be granted by the local in-suite assistant and can be granted or revoked as needed using an on-premises computer installed with the assistance touch interface. “Control mode” access may be granted on-demand or prior to acquisition to access the scanner. TechLive offers a secure collaboration platform with live audio and video, enabling remote acquisition and seamless collaboration among healthcare professionals. TechLive is vendor-neutral and compatible with existing imaging devices, including Ultrasound (US), Magnetic Resonance Imaging (MRI), Computer Tomography (CT), and Positron Emission Tomography (PET/CT).

5. INTENDED USE/ INDICATIONS FOR USE

TechLive is a software application intended to provide remote access for real-time image acquisition, assistance, review, monitoring and standardization of imaging devices across multiple locations. It is a vendor neutral solution allowing read-only or full access control to connected devices. Tech Live is also intended for training of medical personnel working on medical imaging devices. TechLive is not intended for diagnostic use.

Intended Users

TechLive intended for the following user profiles/user roles:

- Remote Users: Healthcare professionals responsible for acquiring diagnostic images using connected imaging devices.
- In-Suite Assistants: Healthcare professionals responsible for managing or supporting in-room imaging procedures.
- IT Administrative Personnel: Individuals responsible for implementation, service and maintenance, access control and general management of the software.

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Intended Use Environment

Healthcare Facility

Intended Patient Populations

TechLive does not have a limitation concerning the patient population (e.g., age, weight, health, condition).

Warnings and Precautions

TechLive is not intended for diagnostic purposes. Data accessed through the platform should only be used for operational support and remote collaboration.

6. PREDICATE DEVICE COMPARISON

Both the subject and the predicate device have similar indications for use, technical characteristics, principles of operation and the same patient population. Both devices are software applications, intended for remote scanning, support, assistance, review, monitoring, and standardization of medical imaging devices across multiple locations. Neither device is intended for diagnostic use. Both devices are vendor-neutral solutions allowing view-only or full access control to connected devices. Although different terminology is used for Intended Users, the clinical users of the predicate device align with those of the subject device. Both devices are intended to be used by healthcare professionals with similar qualifications for remote acquisition of images and IT administrators for the service and maintenance of the software.

The Technological Characteristics of the subject and predicate device are the same or differ only slightly in terminology, except for the following:

Supported Radiological Devices: the subject device cannot be used in combination with radiotherapeutic devices and hence supports only a subset of what the predicate device supports.

Connection Protocols: the subject device uses WebRTC over HTTPS, and the predicate device uses HTTPS over TCP, which provides similar security benefits.

Communication Features: the subject device uses state-of-the-art communication tools, such as USB cameras for live video, which provide the same functionality as those of the predicate device. The subject device does not include a chat function but rather fully relies on audio/video communication. The transfer of audio, video and data signals uses the same protocols as the predicate device, although slightly different terminology is used.

Image Acquisition: Both the subject and predicate device provide remote image acquisition. Where the subject device has limitations for acquisition specific to the allowable connected software of the modality, the predicate device states limitations specific to CT acquisition. The subject device cannot be used in combination with radiotherapeutic devices and hence supports only a subset of what the predicate device supports.

Device Limitations: Both the subject and predicate device have similar limitations regarding their use. The predicate device has an additional limitation related to the use of KVM Switches when used with 3rd party modalities.

Performance and Non-clinical testing have been completed ensuring that the differences between the subject and predicate device do not affect the safety and effectiveness of the proposed subject device.

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Comparison between the subject device and predicate device demonstrate the functional and performance equivalence of the products. The minor differences in technological characteristics and Indications for Use do not raise new issues of safety and effectiveness. Therefore, TechLive is substantially equivalent to the currently marketed predicate device.

7. PERFORMANCE DATA

Clinical Testing

TechLive has not been subject to clinical testing. All performance testing was conducted as part of the verification and validation activities for the medical device.

Summary of Non-Clinical Testing

Non-clinical testing was conducted during product development. The design and development of TechLive conforms to the following FDA-recognized standards and guidance documents:

- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices (#5-125)
- IEC 62304:2015 – Medical Device Software – Software Life Cycles Processes (#13-79)
- IEC 82304-1 – Health Software – Part 1: General Requirements for product safety (#13-97)
- FDA Guidance: Content of Premarket Submissions for Device Software Functions (June 2023)
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 2023)

Usability Studies

Human Factor/Usability Engineering activities has been conducted for TechLive using both Formative and Summative testing. The results demonstrate that users are able to successfully and safely perform critical tasks with high efficiency and minimal errors, affirming that TechLive meets its intended use criteria and supports effective remote diagnostic operations across imaging modalities.

Vendor Neutrality and Multi-Vendor Validation Testing

Verification and validation testing of TechLive successfully demonstrated vendor-neutral functionality and interoperability across scanner types and manufacturers. The device met all specifications for functional, long-duration and interoperability tests, validating seamless console operation.

Non-clinical Verification and Validation testing

Non-clinical Verification and Validation testing was conducted in accordance with applicable standards and internal design procedures. Verification and validation demonstrated that the TechLive software, as designed and implemented, meets all pre-defined performance specifications, user needs and its intended use, showing that the TechLive is substantially equivalent to the predicate device.

8. CONCLUSION

The testing conducted to support this submission confirms that TechLive is as safe and as effective as the predicate device. The minor differences between the subject and predicate device do not alter the intended use of the device and do not raise different questions in terms of safety and effectiveness when used as

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labeled. Therefore, the information presented in this 510(k) submission demonstrates that TechLive is substantially equivalent to the legally marketed predicate device.