July 17, 2026

Stryker Endoscopy
Lucas Dan
Senior Staff Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: DEN250040
Trade/Device Name: SportSuite Vision Software
Regulation Number: 21 CFR 888.1150
Regulation Name: Arthroscopic or orthopedic endoscopic intraoperative augmented reality video see-through display system
Regulatory Class: Class II
Product Code: SIT
Dated: September 2, 2025
Received: September 2, 2025

Dear Lucas Dan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the SportSuite Vision Software, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> SportSuite Vision Software is indicated for the intraoperative display of arthroscopic video and medical imaging during femoroacetabular impingement and labral repair hip arthroscopy procedures, and the display of the same information as presented by the HipCheck software and HipMap FAI Analysis. When using the device, surgical tasks are performed through a video see-through augmented reality head mounted display.
>
> Virtual images from video see-through augmented reality shall be used by the surgeon in conjunction with the use of traditional monitors by other Operating Room staff.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SportSuite Vision Software, and substantially equivalent devices of this generic type, into Class II under the generic name arthroscopic or orthopedic endoscopic intraoperative augmented reality video see-through display system.

FDA identifies this generic type of device as:

> **Arthroscopic or orthopedic endoscopic intraoperative augmented reality video see-through display system**. This device consists of augmented reality software on a head-mounted display that displays arthroscopic or endoscopic video and medical imaging during orthopedic surgery. The device is intended to intraoperatively augment visualization with contextually relevant information and data, including that received from other devices.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 2, 2025, FDA received your De Novo requesting classification of the SportSuite Vision Software. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SportSuite Vision Software into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the SportSuite Vision Software can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Device failure/malfunction from software leading to malpositioning of tissue and other devices, tissue injury, the need for re-operation, latency in display and prolonged operative time	Non-clinical performance testing Labeling Software verification, validation, and hazard analysis
Use error/improper device use leading to malpositioning of tissue and other devices	Non-clinical performance testing Human factors/ usability testing Labeling
Electrical shock	Electrical safety testing
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing Wireless coexistence testing
Infection	Reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the arthroscopic or orthopedic endoscopic intraoperative augmented reality video see-through display system is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including:
  (i) Validation of system-level procedural accuracy in a cadaveric model;
  (ii) Validation of patient monitoring and visualization under worst-case conditions for intended anatomical locations;
  (iii) System validation of the head-mounted display (HMD) with imaging data, contextually relevant information, and other displays available during surgery, in simulated use with a relevant clinical model (e.g., cadaver) while performing worst-case intraoperative tasks; and
  (iv) System-level testing with each compatible HMD that evaluates color accuracy, image latency, distortion, contrast, spatial accuracy, ambient light response, and live video quality.

(2) Human factors/usability testing must demonstrate that the intended user(s) can correctly use the device and perform the intended surgical tasks accurately, based on the instructions for use.

(3) Software verification, validation, and hazard analysis must be performed.

(4) Performance data must demonstrate the electrical safety, electromagnetic compatibility, mechanical safety, thermal safety and wireless coexistence of the device.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

(6) Labeling must include:
  (i) A summary of the technical parameters of the device;
  (ii) An instruction for users to familiarize themselves and become comfortable with the device prior to use during surgery;
  (iii) Identification of compatible equipment, including controllers, HMD features, and surgical procedure-specific components;
  (iv) A summary of the surgical tasks that were validated to be successfully performed with this device;
  (v) Validated methods and instructions for reprocessing any reusable components and disposal instructions for single-use components;
  (vi) Conditions of use that may impact the accuracy, reliability, or functionality of the device;
  (vii) Mitigations for users' eye conditions or other pre-existing medical conditions that may impact visual motion sensitivity; and
  (viii) An instruction to have a traditional monitor(s) available as a backup to the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the arthroscopic or orthopedic endoscopic intraoperative augmented reality video see-through display system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Sai Deepa Rayaprolu at saideepa.rayaprolu@fda.hhs.gov.

Sincerely,

Laurence D. Coyne -S

Digitally signed by Laurence D. Coyne -S

Laurence D. Coyne, Ph.D.
Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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