July 6, 2026

Smith & Nephew, Inc.
Pooja Dalvi
Principal Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: DEN250037
Trade/Device Name: TESSA Spatial Surgery System; INTELLIO Tablet (72205455)
Regulation Number: 21 CFR 888.4561
Regulation Name: Intra-articular orthopedic stereotaxic navigation instrument
Regulatory Class: Class II
Product Code: SIQ
Dated: August 21, 2025
Received: August 22, 2025

Dear Pooja Dalvi:

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 TESSA Spatial Surgery System; INTELLIO Tablet (72205455), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> TESSA◊ Spatial Surgery System:
> TESSA◊ Spatial Surgery System is indicated for use in primary anterior cruciate ligament (ACL) reconstructions in adult and skeletally mature adolescent patients aged 18 years and older in which the use of stereotactic surgery for the planning and navigation guidance of femoral tunnel placement may be appropriate, and where reference to rigid anatomical bony structures can be determined.
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> INTELLIO Tablet:
> The Smith+Nephew INTELLIO◊ Tablet is intended to provide wired or wireless remote control of Smith+Nephew compatible surgical and endoscopic devices within the operating room including camera/camera control unit, patient information system, mechanical resection system, fluid management system, RF COBLATION◊ system, and the orthopedic guided navigation system such as the TESSA◊ Spatial Surgery System.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the TESSA Spatial Surgery System; INTELLIO Tablet (72205455), and substantially equivalent devices of this generic type, into Class II under the generic name intra-articular orthopedic stereotaxic navigation instrument.

FDA identifies this generic type of device as:

> **Intra-articular orthopedic stereotaxic navigation instrument**. An intra-articular orthopedic stereotaxic navigation instrument is a device consisting of a rigid frame of reference with a calibrated guide mechanism and fiducial markers temporarily affixed to anatomical structures within the intra-articular space. The markers are continuously tracked for precisely positioning instruments or 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 August 22, 2025, FDA received your De Novo requesting classification of the TESSA Spatial Surgery System; INTELLIO Tablet (72205455). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the TESSA Spatial Surgery System; INTELLIO Tablet (72205455) 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 TESSA Spatial Surgery System; INTELLIO Tablet (72205455) 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:

Identified Risks to Health	Mitigation Measures
Device failure/malfunction leading to malpositioning of tissue and other devices, re-operation, tissue injury, and prolonged operative time	Non-clinical performance testing Labeling
Device malfunction resulting from software error or failure	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
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Reprocessing validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the intra-articular orthopedic stereotaxic navigation instrument 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) Simulated use testing in a clinically relevant model (e.g., cadaver or animal) that evaluates system-level accuracy, procedural accuracy, and marker integrity;
  (ii) System image quality and latency testing; and
  (iii) System, component, and inter-device compatibility testing.

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

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

(4) Human factors/usability testing must demonstrate that the intended user(s) can correctly use the device based on the instructions for use.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

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

(7) The patient-contacting components of the device must be demonstrated to be sterile.

(8) Performance data must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(9) Labeling must include:
  (i) A summary of the technical parameters of the device, including accuracy and precision;
  (ii) Identification of compatible surgical equipment, imaging modalities, accessories, and components;
  (iii) Validated instructions for reprocessing any reusable components, or disposal instructions for single use components;
  (iv) A shelf life or service period; and
  (v) Conditions of use that may impact the accuracy, reliability, or functionality of the device.

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 intra-articular orthopedic stereotaxic navigation instrument 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 Joanne Ly, Ph.D. at 240-402-7596.

Sincerely,

Ronald P. Jean -S

for Laurence D. Coyne, Ph.D.
Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health