July 12, 2021

Ortho-Space Ltd.
℅ Ms. Katie Farraro
Staff Regulatory Affairs Specialist
Stryker
7 Halamish Street
Caesarea, 3079579
Israel

Re: DEN200039
Trade/Device Name: InSpace™ Subacromial Tissue Spacer System
Regulation Number: 21 CFR 888.3630
Regulation Name: Resorbable shoulder spacer
Regulatory Class: Class II
Product Code: QPQ
Dated: June 12, 2020
Received: June 12, 2020

Dear Ms. Farraro:

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 InSpace™ Subacromial Tissue Spacer System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The InSpace™ Subacromial Tissue Spacer System is indicated for the treatment of patients with massive, irreparable full-thickness torn rotator cuff tendons due to trauma or degradation with mild to moderate gleno-humeral osteoarthritis in patients greater than or equal to 65 years of age whose clinical conditions would benefit from a treatment with a shorter surgical time compared to partial rotator cuff repair.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the InSpace™ Subacromial Tissue Spacer System, and substantially equivalent devices of this generic type, into Class II under the generic name resorbable shoulder spacer.

FDA identifies this generic type of device as:

> **Resorbable shoulder spacer**. A resorbable shoulder spacer is intended to act as a temporary spacer, creating a physical barrier between tissues in the shoulder, for the treatment of massive irreparable rotator cuff tears.

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 June 12, 2020, FDA received your De Novo requesting classification of the InSpace™ Subacromial Tissue Spacer System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the InSpace™ Subacromial Tissue Spacer System 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 InSpace™ Subacromial Tissue Spacer System 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:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk to Health	**Mitigation Measures**
No improvement in shoulder function and pain reduction due to device failure from: ▪ Device migration ▪ Device malposition ▪ Device collapse	Clinical performance testing Non-clinical performance testing Animal performance testing Labeling
Increased risk of adverse events (AEs) of the index shoulder (e.g., pain, spasm, and swelling, subsequent medical and surgical treatments secondary to disease progression)	Clinical performance testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Animal performance testing Non-clinical performance testing Labeling
Infection	Sterilization validation Pyrogenicity testing Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the resorbable shoulder spacer is subject to the following special controls:

1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    i. Evaluation of improvement of shoulder function and reduction of symptoms (e.g., pain and function) for the indications for use; and
    ii. Evaluation of relevant adverse events.
2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    i. Integrity testing of the device, including mechanical and chemical stability; and
    ii. Characterization of the device degradation profile.
3) Animal performance testing must include evaluation of the following:
    i. Adverse effects, including gross necropsy and histopathology; and
    ii. Device degradation to verify in vitro versus in vivo degradation correlation.
4) All patient-contacting components of the device must be demonstrated to be biocompatible.
5) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.
6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
7) Labeling must include the following:
    i. Instruction for use, including specific instructions regarding device selection and placement;
    ii. A detailed summary of the clinical performance testing with the device, including procedure- and device-related complications or adverse events; and
    iii. A shelf life.

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 resorbable shoulder spacer 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 systems (QS) regulation (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.

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 Farzana Sharmin, Ph.D. at 301-796-4067.

Sincerely,

FDA Vincent J. Devlin -S

for
CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health