April 10, 2023

Moximed, Inc.
Nancy Issac
Regulatory Counsel and VP of Quality
46602 Landing Parkway
Fremont, California 94538

Re: DEN220033
Trade/Device Name: MISHA™ Knee System
Regulation Number: 21 CFR 888.3610
Regulation Name: Medial knee implanted shock absorber
Regulatory Class: Class II
Product Code: QVV
Dated: June 3, 2022
Received: June 6, 2022

Dear Nancy Issac:

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 MISHA™ Knee System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The MISHA™ Knee System is indicated for patients with medial compartment knee osteoarthritis that have failed to find relief in surgical and/or non-surgical treatment modalities and are still experiencing pain that interferes with activities of daily living and are also unwilling to undergo or ineligible for total knee replacement due to age or absence of advanced osteoarthritis.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the MISHA™ Knee System, and substantially equivalent devices of this generic type, into Class II under the generic name medial knee implanted shock absorber.

FDA identifies this generic type of device as:

> **Medial knee implanted shock absorber.** A medial knee implanted shock absorber is a device implanted outside of the knee capsule extending from the distal femur to the proximal tibia. It is intended to reduce loads on the intra-articular medial joint surface to improve symptoms of osteoarthritis. The device employs a shock absorbing mechanical system and is biomechanically stabilized by plates and screws. The device is not intended to span the lateral knee.

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 6, 2022, FDA received your De Novo requesting classification of the MISHA™ Knee System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MISHA™ Knee 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 MISHA™ Knee 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:

Risks to Health	**Mitigation Measures**
Implant failure to improve osteoarthritis symptoms, including pain and discomfort	Clinical data Non-clinical performance testing Training
Pain and discomfort due to implant	Clinical data Training
Loss of implant integrity leading to loss of fixation and reoperation	Clinical data Non-clinical performance testing
Ligament or nerve injury resulting in motor and/or sensory damage	Clinical data Training
Scar formation	Clinical data Training
Infection	Sterilization validation Reprocessing validation Shelf-life testing Pyrogenicity testing Labeling
Adverse tissue reaction due to • Device materials • Fretting and corrosion • Wear particulates	Biocompatibility evaluation Non-clinical performance testing

In combination with the general controls of the FD&C Act, the medial knee implanted shock absorber is subject to the following special controls:

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
    (i) Evaluation of improvement of knee function and reduction of osteoarthritis symptoms, including pain and function; 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) Evaluation of the mechanical function and durability of the implant (including evaluation of absorber unloading capacity, fretting and corrosion, static strength, wear analysis, and fatigue testing); and
    (ii) Evaluation of worst-case device range of motion.
(3) The patient-contacting components of the device must be demonstrated to be biocompatible.
(4) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.
(5) Performance data must validate the reprocessing instructions for the reusable components of the device.
(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) A training program must be included so that upon completion of the training program, the user can safely and successfully implant the device.
(8) Labeling must include the following:
    (i) Validated methods and instructions for reprocessing of any reusable components; and
    (ii) 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 medial knee implanted shock absorber 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 post marketing 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 Michael Torres at (240) 402-7293.

Sincerely,

Raquel A. Peat -S

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