January 10, 2025

Askorn Medical
Denis Pichon
General Manager
44c rue de Bray
Cesson-Sévigné, 35510
France

Re: K243477
Trade/Device Name: Universal Tendon Spacer
Regulation Number: 21 CFR 888.3025
Regulation Name: Passive Tendon Prosthesis
Regulatory Class: Class II
Product Code: HXA
Dated: November 5, 2024
Received: November 8, 2024

Dear Denis Pichon:

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,

Christopher Ferriera, MS
Assistant 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

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)*

K243477

Device Name

Universal Tendon Spacer

Indications for Use *(Describe)*

Universal Tendon Spacer is a medical device used in the reconstruction of the flexor and extensor tendons of the hand. The device is implantable for 2 to 6 months and intended for single use.

This device is used for:
Adherent or mutilated tendons following trauma or a primary repair which has failed. Absence of the tendon sheath. Non-functioning, mutilated or adherent tendon pulleys. Ruptured tendons.
The patient must be in good health with sufficient tissue cover. Sufficiently healthy joints, bone marrow and adequate vascular and neuro-muscular conditions are also necessary to facilitate a definite functional improvement using this reconstruction technique. The patient must be cooperative, especially concerning the need for rehabilitation measures.

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.

510(k) #: K243477

510(k) Summary

Prepared on: 2024-11-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Askorn Medical
Applicant Address	44c rue de Bray Cesson-Sévigné 35510 France
Applicant Contact Telephone	+33223355335
Applicant Contact	Mr. Denis Pichon
Applicant Contact Email	d.pichon@askorn.bzh

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Universal Tendon Spacer
Common Name	Passive tendon prosthesis
Classification Name	Prosthesis, Tendon, Passive
Regulation Number	888.3025
Product Code(s)	HXA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K000019	Single Size Tendon Spacer	HXA

Device Description Summary

21 CFR 807.92(a)(4)

Universal Tendon Spacer (UTS) is a medical device made of silicone for temporary implantation (two to six months) for use in the two-stage reconstruction of the flexor and extensor tendons of the hand. When implanted, UTS is in contact with the tissues and bones of the fingers for a long-term contact duration (>30 days).

This medical device contributes to the rehabilitation of the digital canal by creating a neo-sheath which should be as large as possible depending on the patient's anatomy. It is the reaction of the body with the silicone which makes it possible to obtain the synovial neo-sheath which will receive, during the second operative time, a tendon of the patient. Due to the formation of this neo-sheath the tendon will be able to slide again in the sheath and will make the finger of the patient work.

The Universal Tendon Spacer is a single size ovoid-shaped rod whose diameter gradually widens over its entire length. The rule is for the larger diameter to always be twice that of the smaller diameter.

The principle is the same as those of rival manufacturers, the main difference being that the four different sizes generally provided are all available on one single rod. The UTS is made of long-term high performance implantable silicone to which barium sulfate has been added to make the rod radio-opaque for X-ray examination. Raw materials of Universal Tendon Spacer meet USP Class VI test requirements.

Only one reference exists for this device, and it is not intended to be assembled with any other device.

The intended patient population is adults and children.
The device is for single use only and is provided sterile.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

Universal Tendon Spacer is a medical device used in the reconstruction of the flexor and extensor tendons of the hand. The device is implantable for 2 to 6 months and intended for single use.

This device is used for:
Adherent or mutilated tendons following trauma or a primary repair which has failed. Absence of the tendon sheath. Non-functioning, mutilated or adherent tendon pulleys. Ruptured tendons.
The patient must be in good health with sufficient tissue cover. Sufficiently healthy joints, bone marrow and adequate vascular and neuro-muscular conditions are also necessary to facilitate a definite functional improvement using this reconstruction technique. The patient must be cooperative, especially concerning the need for rehabilitation measures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the exact same indications for use than the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The Universal Tendon Spacer is technology substantially equivalent to the predicate device in material, design features, size and mechanical strength.

The subject and predicate device are based on the exact same technological characteristics:
- Function and principle of operation: designed for the two-step tendon reconstruction surgery of the hand
- Design: unique size implant with an oval cross-section, exact same design and dimensions
- Material: same medical-grade silicone elastomer and barium sulfate from the same raw material supplier
- Manufacturing process: same injection-molding process (same mold used), same final cleaning and packaging process, same sterilization process (gamma irradiation)
- Mechanical strength: mechanical testing was performed, and results indicate that the Universal Tendon Spacer manufactured by Askorn is equivalent to the predicate device.
- Both devices are provided sterile, are for single use only, and are biocompatible as per ISO 10993-1

Both the proposed and predicate designs are intended to function as a temporary implant for the two-stage tendon reconstruction of the hand and are manufactured from the same materials with the same manufacturing process.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Mechanical strength test was performed to compare the Universal Tendon Spacer strength with the predicate device, according to NF EN ISO 527-2. Tensile strength, elongation and strain at break were found to be equivalent to the predicate device.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing:
The biocompatibility evaluation for the Universal Tendon Spacer was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:
• Cytotoxicity
• Sensitization
• Irritation
• Pyrogenicity

The Universal Tendon Spacer is considered as an implant tissue and bone contacting for a duration of more than 30 days. The UTS materials conforms to USP Class VI requirements.

Packaging testing:
Package tests were performed to validate package integrity and shelf-life claims (5 years). The following test were carried out after real-time and accelerated aging:
• Visual inspection of the packaging
• Dye penetration (integrity test)
• Seal strength test

The results show that the packaging type double blister for Universal Tendon Spacer has correct integrity, resistance and peelability proprieties after sterilization and 5 years aging, according to the relevant chapters of ISO 11607-1, ISO 11607-2 and NF EN 868-5 standards.

From the above provided information and the history of the subject device, Universal Tendon Spacer is a ssafe, as effective, and performs as well as the legally marketed device.

CONCLUSION:
The design characteristics of the device do not raise any new types of questions of safety or effectiveness. The non-clinical data support the safety of the device. The Universal Tendon Spacer is substantially equivalent to the predicate marketed device based on a comparison of intended use, indications for use, design and technological characteristics. From the evidence submitted in this 510(k) Premarket Notification, the device is as safe, as effective and performs at least as well as the predicate device.