August 17, 2023

Anika Therapeutics, Inc.
Wei Zhao
Executive Director, Regulatory Affairs
32 Wiggins Ave.
Bedford, Massachusetts 01730

Re: K223538
Trade/Device Name: Integrity™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX
Dated: July 18, 2023
Received: July 18, 2023

Dear Wei Zhao:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -S

Jesse Muir, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223538

Device Name
Integrity Implant

Indications for Use *(Describe)*

The Integrity Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. SUBMITTER

Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730

Phone: 781-457-9000

Contact Person: Wei Zhao, Executive Director, Regulatory Affairs
Date Prepared: August 15, 2023

II. DEVICE

Name of Device: Integrity™ Implant
Common or Usual Name: Tendon Protector
Classification Name: Mesh, Surgical (878.3300)
Regulatory Class: II
Product Code: OWX

III. PREDICATE DEVICE

Collagen Tendon Sheet, K112423

IV. REFERENCE DEVICES

Versawrap Tendon Protector, K160364
Tapestry Biointegrative Implant, K201572
HyaloMatrix PA, K073251
Pitch-Patch, K211563

V. DEVICE DESCRIPTION

The Integrity Implant is a partially resorbable mesh. The Integrity Implant is designed to provide an augmentation layer over an injured tendon. The patch is comprised of a knitted porous mesh of resorbable Hyaff multifilament fibers and non-resorbable poly(ethylene terephthalate) [PET] multifilament fibers. The patch is provided sterile, for single use only, in a variety of sizes in a thermoformed tray with peelable lid and outer polymer packaging. The device is an easy-to-handle, pliable, nonfriable, porous patch in both the dry and hydrated state.

The Integrity Implant will be made available in 2 sizes:

- 20mm X 25mm
- 25mm X 30mm

The mechanism of action of the Integrity Implant is to function as a protective layer by keeping damaged tendon physically separated from surrounding tissues during healing. It is not intended to replace substantial loss of tendon. Over the course of 4-6 months, the device will be mostly resorbed by the body.

The patch will be used in a surgical environment by a board-certified surgeon. It will be implanted using a standard open or arthroscopic access surgical procedure. It will be fixated at one end to the bone via fixation anchor and at the other end to the repaired tendon via suture or fixation anchor.

VI. INDICTATIONS FOR USE

The Integrity Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A table comparing the key features of the subject and predicate device is provided below.

	Integrity Implant (Subject Device)	Collagen Tendon Sheet (Predicate Device)	Discussion
510(K) No.	TBD	K112423	N/A
Device Class	Class II	Class II	Same
Product Code	OWX	FTM	Same
Classification	Mesh, Surgical	Mesh, Surgical	Same
Intended Use/ Indication for Use	Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Same
Material Type	Hyaff and PET	Type I Collagen	See “Discussion of Differences” below
Resorbable	Partial	Yes	See “Discussion of Differences” below
Configuration	Sheet	Sheet	Same
Nominal Sizes	20 X 25 mm (2.0 X 2.5 cm) 25 X 30 mm (2.5 X 3.0 cm)	2 X 2.5 cm 2.5 X 3 cm	Same
Reusable	No	No	Same
Packaging	Tray within a peel pouch	Double peel package	See “Discussion of Differences” below
Sterilization	Gamma Irradiation	Gamma Irradiation	Same

Discussion of Differences

Material:
The subject device differs from the predicate in its material type. The subject device is composed of Hyaff, (esterified hyaluronic acid [HA]) and PET. The predicate device is composed of Type I Collagen derived from bovine Achilles' tendon. The PET (natural and with D&C Blue No. 6) used in the subject device has been added for structural integrity and increased mechanical strength. The PET with D&C Blue No. 6 was added for visibility during surgical procedures. Despite differences in the material type, the subject device has been proven substantially equivalent per performance testing.

Resorption:
The predicate device is considered fully resorbable, while the subject device is considered partially resorbable. The majority of the subject device (Hyaff portion) will be resorbed with the PET remaining. PET has a long history of demonstrated biocompatibility and is used in numerous FDA approved implantable devices that include high-strength polyester sutures.

Packaging:
The predicate and subject device both have similar packaging as both packaging systems consist of a double peel package. The predicate device has a secondary sterile barrier that also provides additional protection. Both packaging configurations ensure sterile integrity of the applicable device.

VIII. PERFORMANCE DATA

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

Biocompatibility testing
The Integrity Implant is characterized according to ISO 10993-1 as an implant medical device having long-term contact duration (≥30d) to tissue/bone. The biocompatibility evaluation for the Integrity Implant was conducted in accordance with the FDA guidance document issued on September 4, 2020: "Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The endpoints of biological evaluation included the following tests:

- Chemical Characterization/Toxicological Risk Assessment
- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Material Mediated Pyrogenicity
- Bacterial Endotoxin (LAL)
- Genotoxicity
- Implantation/Biodegradation

Performance Testing - Bench
The following bench tests were performed on the Integrity Implant:

- Sterility
- Shelf Life
- Dimensions
- Thickness
- Mesh Basis Weight/Density
- Mesh Knit Characteristics
- Pore Size
- Patch Stiffness
- Patch Compliance
- Tear Resistance
- Suture Pull-out/Retention Strength
- Bacterial Endotoxin Limits
- Residual Solvents

Performance Testing - Animal

The purpose of the study was to characterize bone ingrowth, local tissue responses and biomechanical effectiveness of repair of the rotator cuff with the Integrity Implant against the predicate, Collagen Tendon Sheet (Regeneten), and a control. An adult bilateral infraspinatus model with time points at 6, 12 and 26 weeks was used. A total of forty-seven (47) skeletally mature sheep were enrolled. The specific aims of the study at 6, 12 and 26 weeks were:

- To evaluate the gross macroscopic appearance
- To evaluate the radiographic changes based on AP and lateral radiographs and Micro-Computed Tomography.
- To evaluate the mechanical properties of the repair.
- To evaluate and compare the histological responses.

There were no study related complications or premature deaths in this study. All surgical procedures were completed without incident. No adverse reactions were noted in the in-life phase of the study and all animals ambulated normally throughout the study periods. Gross dissections and harvest did not reveal any adverse reactions in the subject, predicate, or control groups. Blood work and distant organ pathology were normal for all animals in this study.

Radiographic endpoints using radiographs and micro-computed tomography and 3T MRI scanning demonstrated no adverse reactions.

Tensile testing of the repaired rotator cuff demonstrated that the subject device and the predicate device performed substantially equivalent and, did not reveal any differences between the groups.

Histology results from the current study demonstrated that the subject and predicate devices resorb with time providing a substantially equivalent regenerative scaffold for new collagenous tissue formation. Both the Subject and Predicate device supported new collagen tissue formation via fibroblasts that infiltrated over and within the devices.

No questions regarding the efficacy of the Integrity Implant were raised and the subject and predicate devices can be viewed as substantially equivalent based on the outcomes of the animal study.

Clinical Data
No clinical studies were conducted using the Integrity Implant prior to the 510(k) submission.

Conclusions
The Integrity Implant is considered substantially equivalent to the Collagen Tendon Sheet. The two devices have the same indication. Both devices have similar characteristics. Testing data also indicated the performance characteristics of the two devices is substantially equivalent. Any differences in characteristics, such as the material, do not raise additional questions of safety and effectiveness.