June 17, 2025

Anika Therapeutics, Inc.
Shajunath Nirupama
Sr. Regulatory Affairs Specialist
32 Wiggins Ave
Bedford, Massachusetts 01730

Re: K250997
Trade/Device Name: Integrity™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX
Dated: April 21, 2025
Received: April 22, 2025

Dear Shajunath Nirupama:

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 FERREIRA -S

Christopher Ferreira, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250997

Please provide the device trade name(s).

Integrity™ Implant

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

[As required 21 CFR 807.92]

Date Prepared: June 16, 2025
510(k) Number: K250997

Submitter Name

Anika Therapeutics, Inc.

32 Wiggins Avenue

Bedford, MA 01730

Establishment No: 3007093114

Contact Person

Shajunath Nirupama

Sr. Regulatory Affairs Specialist

Phone: 781-457-9230

Email: snirupama@anika.com

General Information

General Information of Subject Device	
Trade Name	Integrity™ Implant
Common Name	Tendon Protector
510(k) Submitter	Anika Therapeutics, Inc
Regulatory Class	II
Classification Name	Mesh, Surgical
Regulation	878.3300
Product Code	OWX
Review Panel	Orthopedic
Predicate 510(k) Number	Integrity™ Implant- K223538

Reason for Submission

The purpose of this 510(k) is to obtain clearance for new sizes for Integrity Implant with same indication for use as predicate device as stated herein.

Device Description

The Integrity™ Implant is designed to provide an augmentation layer over an injured tendon. The implant is a knitted porous mesh comprised of a single composite layer of resorbable Hyaff-11 multifilament fibers and non-resorbable polyethylene terephthalate (PET) multifilament fibers. The implant is easy to handle, pliable, nonfriable, and porous in both the dry and hydrated state. The implant is provided sterile, for single use only, in a thermoformed tray with peelable lid and outer polymer packaging.
The subject of the 510(k) is the addition of two new sizes:

- 25mm x 60mm
- 40mm x 60mm

The device will be used in a surgical environment by a trained surgeon. It will be implanted using a standard open or arthroscopic access surgical procedure. It will be secured to the tendon or tendon/bone by applying fixation.

Indications 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.

Substantial Equivalence Summary

The key features of the subject and predicate device, Integrity Implant is compared and provided in the Table below:

Device Name	Integrity Implant (Subject Device)	Integrity Implant (Predicate Device)	Discussion
510(K) No	K250997	K223538	N/A
Manufacturer	Class II	Class II	Same
Device Class	Mesh, Surgical	Mesh, Surgical	Same
Product Code	OWX	OWX	Same
Regulation	878.3300	878.3300	Same
Indications 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 + PET	Hyaff +PET	Same
Resorbable	Partial	Partial	Same
Dimensions/ Sizes	25 X 60 mm (2.5 X 6.0 cm) 40 X 60 mm (4.0 X 6.0 cm)	20 X 25 mm (2.0 X 2.5 cm) 25 X 30 mm (2.5 X 3.0 cm)	Larger
Reusable	No	No	Same
Packaging	Tray within a peel pouch	Tray within a peel pouch	Same
Sterilization	Gamma Irradiation	Gamma Irradiation	Same

Performance Data (Bench)

A risk analysis was conducted for the new dimensions/sizes of Integrity Implant and following performance testing completed to demonstrate the substantial equivalence:

- Dimensions/Sizes
- Mesh/Device Thickness
- Mesh Basis Weight/Density
- Device Stiffness
- Mesh Compliance
- Sterility

All other past verification testing: suture retention, tear resistance, hydration fluid compatibility, bacterial endotoxin, residual solvents, and Hyaff Degree of esterification, conducted for predicate device(K223538) remains applicable for the subject device.

Performance Data (Animal Testing)

Results of original animal study submitted in 510(k) K223538 is applicable to the subject device since the subject device and predicate device have same indication for use, material composition and sterilization.

Performance Data (Clinical Testing)

No clinical study was conducted for the Predicate device and clinical study not deemed necessary for subject device.

Biocompatibility

The subject device and the predicate device have same material, manufacturing process, and sterilization parameters. A biological risk assessment on the subject device confirmed that the new sizes meet all biological endpoints for a tissue/bone contacting implant device for permanent contact duration for its intended use. Therefore, past biocompatibility tests included in 510(k) K223538 are still applicable.

Conclusions

The new dimensions/sizes of Integrity Implant are considered substantially equivalent to the predicate device, Integrity Implant. The devices have the same indications for use, materials, principle of operation, and characteristics. Testing data also indicated performance characteristics of the proposed dimensions of the Integrity Implant is substantially equivalent to the predicate device. The differences in dimension of the devices do not raise any additional questions of safety or effectiveness.

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