May 8, 2023

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

Re: K222487
Trade/Device Name: Anika Tissue Tack Fixation System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: August 15, 2022
Received: August 17, 2022

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 (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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.05.08 11:03:49 -04'00'

Mark Trumbore
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K222487

Device Name
Anika Tissue Tack

Indications for Use *(Describe)*
The Anika Tissue Tack is indicated for the fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures, such as rotator cuff repair.

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.

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510(K) Summary

[As required by 21 CFR 807.92]

Date Prepared: April 7, 2022

510(k) Number: K222487

Submitter Name

Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730
Establishment No: 3007093114

Contact Person

Shajunath Nirupama
Sr. Regulatory Affairs Specialist
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General Information

Table 1: General Information

General Information of Subject Device	
Trade Name	Anika Tissue Tack Fixation System
Common Name	Tissue Tack
510(k) Submitter	Anika Therapeutics, Inc.
Class	II
Classification Name	Staple, Implantable
Regulation	21 CFR 878.4750
Product Code	GDW
Review Panel	General & Plastic Surgery
Primary Predicate & 510(K)	Rotation Medical Soft Tissue Staple- K131637
Reference Device & 510(K)	OptiFix™ AT Absorbable Fixation System with Articulating Technology - K170278
	TissueTak device - K203117

Device Description

The Anika Tissue Tack Fixation System consists of dart shaped tacks and a delivery instrument. The tissue tacks are comprised of bioabsorbable 82/18 poly(lactic-co-glycolic acid) [PLGA] and dyed with D&C Violet #2. The tissue tacks are designed to provide stable fixation of a prosthetic material or biologics to soft tissues during the healing process and are used in conjunction with a delivery instrument from Anika. The delivery instruments are comprised of surgical grade stainless steels and high temperature plastics and are designed to deliver the tissue tacks. The tissue tacks and delivery instruments are provided sterile for single use only. The tacks are packaged in a caddy within a dual sterile seal configuration.

Indication for Use

The Anika Tissue Tack Fixation System is indicated for the fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures, such as rotator cuff repair.

Substantial Equivalence Summary

Anika Therapeutics has demonstrated that for the purposes of the FDA's regulation of medical devices, the Anika Tissue Tack is substantially equivalent in indications for use, design principles and performance to the predicate device (Rotation Medical Soft Tissue Staple, K131637) and reference devices (OptiFix™ AT Absorbable Fixation System with Articulating Technology - K170278 and TissueTak device, K203117).

Table 2: Substantial Equivalence Comparison

Device Name	Anika Tissue Tack Fixation System Subject Device	Rotation Medical Soft Tissue Staple (RMST) Predicate Device	Comparison
510(k) No:	K222487	K131637	N/A
Product Code	GDW	GDW	Same
Indications for Use	The Anika Tissue Tack Fixation System is Indicated for the fixation of prosthetic or biologic material to soft tissues in various minimally invasive and open surgical procedures, such as rotator cuff repair.	The RMST Staple is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures, such as the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	Substantially Equivalent (see Discussion below)
Color	D&C Violet #2	D&C Violet #2	Same
Physical form	Dart shaped Tack	Staple shaped Tack	Same as reference device (K17027)
Size	6mm, 7mm, 8mm	6.5mm	Substantially

			Equivalent (see Discussion below)
Material	bioabsorbable Purasorb PLG 82/18 (L-lactide/Glycolide Polymer) dyed with D&C Violet No. 2	bioabsorbable Purasorb PLG 82/18 (L-lactide/Glycolide Polymer) dyed with D&C Violet No. 2	Same
Body Contact	Implant (>30 days)	Implant (>30 days)	Same
Sterilization	Gamma Irradiation	Gamma Irradiation	Same
Packaging	Tacks are pre-loaded into a caddy that is inserted into sealed Tyvek and foil pouches and inserted into a carton.	Tacks are pre-loaded into a caddy that is inserted into sealed Tyvek and foil pouches and inserted into a carton.	Same

Discussion

Indications for Use Statement:

The subject device and predicate device are used similarly to aid in the management of the tendon injuries, such as rotator cuff repair, by affixing a prosthetic material to tissue. The subject device can also affix biologic materials to tissues to aid in the management of the tendon injuries. The subject device has been mechanically tested for this additional indication and no concerns related to the safety and effectiveness were raised. Additionally, the reference device, TissueTak by Via Surgical Ltd. cleared under K203117 is also intended for fixation of prosthetic or biologic material to soft tissues.

Technological Characteristics:

The subject device ranges in size from 6-8mm in length to account for the variations in tendon thickness.

However, subject device's 6-8mm range reflects a nomenclature difference in comparison with predicate and reference devices, as Anika is using the overall length of the device in its naming convention. The longest "depth of purchase" of 6.5mm (for 8mm total length) is the same as the 6.5mm "depth of purchase" of the predicate device and reference device (K170278). Mechanical evaluations have demonstrated no significant difference in pull out or shear strength for varying shaft lengths. Therefore, the device length as described does not affect device safety and effectiveness compared to the predicate and reference devices.

In degradation testing results show that both the subject device and predicate device are identical in degradation time and are substantially equivalent. The differences in the shape and size of subject device versus the predicate does not raise any concerns in comparison to the predicate device as demonstrated by mechanical evaluation.

Performance Testing Summary

The following non-clinical tests and/or analysis were performed for the subject device to demonstrate the safety and effectiveness along with substantial equivalence to the predicate device:

- Mechanical retention strength, tensile & shear
- Degradation testing including mass loss, molar mass and mechanical evaluation.
- Insertion and removal evaluation
- Biocompatibility Testing
- Bacterial endotoxin limit test

Clinical Testing Summary

No clinical testing was submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence for the Anika Tissue Tack Fixation System.

Conclusion

All similarities and differences described above were evaluated. Based on the justifications described in the subsequent sections of this submission, none of the differences raised significant concern regarding the safety or efficacy of the devices. Therefore, Anika Therapeutics has determined that the subject device, Anika Tissue Tack Fixation System is substantially equivalent to the predicate device and is safe and effective for the intended use.

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