May 22, 2023

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

Re: K223860
Trade/Device Name: Integrity™ Bone Staple Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 4, 2023
Received: May 5, 2023

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,

Sara S. Thompson -S

For

Yu-Chieh Chiu, Ph.D.
Acting 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)*
K223860

Device Name
Integrity™ Bone Staple Fixation System

Indications for Use *(Describe)*
The Integrity™ Bone Staple Fixation System is indicated for the fixation of soft tissue grafts or reinforcement meshes to bone during rotator cuff repairs.

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: May 18, 2023,

510(k) Number: K223860

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

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General Information

General Information of Subject Device	
Trade Name	Integrity™ Bone Staple Fixation System
Common Name	Non-Degradable Bone Staple
510(k) Submitter	Anika Therapeutics, Inc.
Class	II
Classification Name	Bone Fixation Fastener
Regulation	21 CFR 888.3040
Product Code	MBI
Review Panel	Orthopedic
Primary Predicate & 510(K)	Rotation Medical Bone Staple (RMB)- K131635 Rotation Medical (Now Smith & Nephew)

Device Description

The Integrity™ Bone Staple Fixation System consists of bone staples and a delivery instrument. The bone staple is a staple-shaped tack with barbed ends and is comprised of non-absorbable poly(ether ether ketone) [PEEK]. The bone staples are designed to provide fixation of soft tissue grafts or reinforcement meshes to bone at surgery and are used in conjunction with a Delivery instrument from Anika. The device is sterilized by radiation with a SAL of 10^{-6}. The bone staples and delivery instruments are provided sterile for single use only. The staples are packaged in a caddy within a dual sterile packaging configuration.

Indication for Use

The Integrity™ Bone Staple Fixation System is indicated for the fixation of soft tissue grafts or reinforcement meshes to bone during rotator cuff repairs.

Substantial Equivalence Summary

Anika Therapeutics has demonstrated that for the purposes of the FDA's regulation of medical devices, the Integrity™ Bone Staple Fixation System is substantially equivalent to the predicate Rotation Medical Bone Staple (K131635) in terms of intended use, material, design principles and performance.

Table 5B- Substantial Equivalence Comparison

Device Name	Integrity ™ Bone Staple Fixation System	Rotation Medical Bone Staple (RMB Staple)	Comparison
510(k) No:	K223860	K131635	N/A
Manufacturer	Anika Therapeutics, inc.	Rotation Medical *(now Smith & Nephew)*	N/A
Classification	II	II	Same
Product code	MBI	MBI	Same
Regulation	21 CFR 888.3040	21 CFR 888.3040	Same
Regulation Description	Bone Fixation Fastener	Bone Fixation Fastener	Same
Panel	Orthopedics	Orthopedics	Same
Indications for Use	The Integrity ™ Bone Staple Fixation System is indicated for the fixation of soft tissue grafts or reinforcement meshes to bone during rotator cuff repairs.	The RMB Staple is indicated for fixation of soft tissue grafts during rotator cuff repair.	Substantially Equivalent (See discussion below)
General Physical form	Staple Shaped Tack	Staple Shaped Tack	Same

Material	PEEK	PEEK	Same
Color	Natural	Natural	Same
Dimensions	11.5 mm in overall height, 6.1 mm width	11 mm in overall height, 6.1mm width	Substantially Equivalent (See discussion below)
Body Contact	Implant (>30 days)	Implant (>30 days)	Same
Packaging	Staples are pre-loaded into a caddy that is packaged in a double pouch	Staples are pre-loaded onto an inserter device in a dual blister pack	See discussion below

Discussion

Indications for Use Statement:

Both the subject and predicate devices are indicated for use during rotator cuff repair surgery to aid in the management tendon injuries. The subject device is designed to affix soft tissue graft or reinforcement mesh to bone which has been mechanically tested and did not raise any concerns on safety and effectiveness. Therefore, there are no additional questions on safety and effectiveness of the subject device as compared to the predicate.

Dimensions:

The difference in dimension is not expected to impact the safety and effectiveness of the device as higher tensile and shear retention strength have been demonstrated in the subject device mechanical performance testing.

Packaging:

The package for both subject and predicate devices are industry standard packages. The Integrity Bone Staples has double sterile barrier packaging. They are pre-loaded into a caddy that is packaged in a double pouch to ensure adequate protection and sterility of the subject device during the shelf life. The predicate device is packaged in a sealed dual blister pack that provides protection and maintains sterility during the shelf life. The difference in package configuration from the predicate does not raise any new concerns of safety and efficacy of the subject device.

Performance Testing Summary

The following non-clinical tests and/or analysis were performed for the Subject Device to demonstrate the substantial equivalence to the predicate devices:

- Mechanical retention strength, tensile & shear
- Insertion and removal evaluation
- Biocompatibility Testing; Cytotoxicity, Sensitization, and Irritation
- Bacterial endotoxin limit test

No clinical or animal data were required to support the substantial equivalence.

Conclusion

The Integrity ™ Bone Staple Fixation System subject to this submission has similar indications for use statement, same intended use, same material, and general physical form. The testing data has demonstrated the performance of the Integrity ™ Bone Staple Fixation System and the predicate device, Rotation Medical Bone Staple is substantially equivalent. Any differences in characteristics do not raise additional questions of safety and effectiveness.
