December 20, 2023

Anika Therapeutics, Inc.
% Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA
Associate Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K231968
Trade/Device Name: Tactoset® Injectable Bone Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: December 1, 2023
Received: December 1, 2023

Dear Dr. Kazemzadeh-Narbat:

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.

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,

Sara S. Thompson -S

For

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices

Enclosure

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*

K231968

Device Name
Tactoset® Injectable Bone Substitute

Indications for Use *(Describe)*

Tactoset® Injectable Bone Substitute is a synthetic, biocompatible bone graft substitute material that hardens and converts to a poorly crystalline hydroxyapatite at body temperature. It is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of bony structure. These defects may be surgically-created osseous defects or defects created from traumatic injury to the bone. The device provides an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process.

Tactoset® Injectable Bone Substitute can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

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

Device Trade Name:	Tactoset
Manufacturer:	Anika Therapeutics, Inc. 32 Wiggins Avenue Bedford, MA 01730
Contact:	Wei Zhao Executive Director, Regulatory Affairs Mobile: (978)888-5948 E-Mail: wzhao@anika.com
Prepared by:	Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA Associate Director, Regulatory Affairs, MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Office: 202.552.6011 mkazemzadeh@mcra.com
Date Prepared:	December 19, 2023
Classifications:	21 CFR §880.3045, Resorbable calcium salt bone void filler device
Class:	II
Product Codes:	MQV
Primary Predicate:	Tactoset (K212083)
Additional Predicates:	Tactoset (K223915) Cerament Bone Void Filler (K201535)

Indications For Use:

Tactoset® Injectable Bone Substitute is a synthetic, biocompatible bone graft substitute material that hardens and converts to a poorly crystalline hydroxyapatite at body temperature. It is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of bony structure. These defects may be surgically-created osseous defects or defects created from traumatic injury to the bone. The device provides an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process. Tactoset Injectable Bone Substitute can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

Device Description:
Tactoset® Injectable Bone Substitute is an injectable, settable osteoconductive calcium phosphate bone graft substitute material. It is provided to the end-user as two components (a dry powder and an aqueous solution in separate pre-loaded syringes) that must be mixed intra-operatively prior to implantation using the supplied mixing system to form a cohesive paste. The dry powder component is composed of the alpha phase of tricalcium phosphate [$Ca_3(PO4)_2$], calcium carbonate [$CaCO_3$], and monocalcium phosphate [$Ca(H_2PO_4)_2$]. The liquid component is composed of sodium phosphate dibasic [Na_2HPO_4], citric acid [$C_6H_8O_7$], hyaluronic acid (HA), Iohexol ($C_{19}H_{26}I_3N_{309}$) and water for injection. Tactoset is provided sterile for single use.

Predicate Device:
Anika Therapeutics, Inc. submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Tactoset is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate:	Tactoset (K212083)
Additional Predicates:	Tactoset (K223915) Cerament Bone Void Filler (K201535)

Performance Testing Summary:
Bench testing data including analytical characterization, chemical composition, physical properties, mechanical testing (Pull-Out, Compressive Strength, Bone Alignment) and animal functional study were conducted for the subject Tactoset and the predicate devices. The results of the study demonstrate substantial equivalence to the predicate devices. The performance of Tactoset containing iohexol radiopacifier was compared to the predicate device, Tactoset (without iohexol), in a rabbit critical sized femoral defect model. At the 26-week timepoint, animal study data demonstrated an average new bone formation of approximately 17% in the Tactoset with iohexol group, and 17% in the Tactoset (predicate) group. Animal study data at 26 weeks demonstrated that approximately 61% of implant material remained in the Tactoset with iohexol group, and 59% remained in the Tactoset (predicate) group, with respect to the geometry of the defect filled with implant material at the time of surgery. At 12 weeks the empty defect contained approximately 6% bone. Clinical performance has not been evaluated.

Substantial Equivalence:
The Subject Device is substantially equivalent to the primary predicate Tactoset (K212083) in terms of material composition, manufacturing process, sterilization, and packaging and both are manufactured in the same facility. The Subject Device and the predicate devices (primary and additional) have the same intended uses, the same product classification and product code (MQV) and have similar "Indications for Use" statements in the extremities and pelvis. The Subject Device and the predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure. The Subject Device and the primary predicate incorporate the same basic design, incorporates similar materials, have identical manufacturing process, identical packaging and are both provided sterile for single-patient, single-use in the same device volume.

The Subject Device and additional predicate Cerament Bone Void Filler (K201535) uses an identical contrast agent/radiopacifier (Iohexol) in its formulation.

No clinical data were required to support the substantial equivalence.

Table 6-1. Substantial Equivalence of the Subject and Predicate Devices.

Information	Subject Device (Tactoset)	Primary Predicate (Tactoset)	Additional Predicate (Tactoset)	Additional Predicate (Cerament)
Manufacturer	Anika Therapeutics, Inc.	Anika Therapeutics, Inc.	Anika Therapeutics, Inc.	Bone Support AB
Trade Name	Tactoset	Tactoset	Tactoset	Cerament Bone Void Filler
510(k) Number	TBD	K212083	K223915	K201535
Product Code	MQV	MQV	MQV	MQV
Device Classification Name	Resorbable calcium salt bone void filler device	Resorbable calcium salt bone void filler device	Resorbable calcium salt bone void filler device	Resorbable calcium salt bone void filler device
Physical Form	Injectable Paste/Putty	Injectable Paste/Putty	Injectable Paste/Putty	Injectable Paste
Device Volume (CC)	4	4	4	5, 10, 18
Mixing Time (Min)	1	1	1	0.5
Working Time (Minute)	7-18	7-18	7-18	3 to 5
Setting Time (Minute)	10	10	10	Not available
Sterility Method	Single Use, Sterile, SAL 10^{-6} Setting Solution: Autoclave and VHP Powder Component: Gamma Irradiation	Single Use, Sterile, SAL 10^{-6} Setting Solution: Autoclave and VHP Powder Component: Gamma Irradiation	Single Use, Sterile, SAL 10^{-6} Setting Solution: Autoclave and VHP Powder Component: Gamma Irradiation	Single Use, Sterile, SAL 10^{-6} Gamma irradiation; Steam; and Ethylene oxide
Pyrogenicity	LAL < 20 EU/device	LAL < 20 EU/device	LAL < 20 EU/device	LAL < 20 EU/device
Packaging	The liquid syringe is double packaged in heat-sealed Tyvek pouches. The cement powder is provided in a mixing syringe packaged in a foil pouch. The foil pouch is then packaged in a plastic tray with a Tyvek lid.	The liquid syringe is double packaged in heat-sealed Tyvek pouches. The cement powder is provided in a mixing syringe packaged in a foil pouch. The foil pouch is then packaged in a plastic tray with a Tyvek lid.	The liquid syringe is double packaged in heat-sealed Tyvek pouches. The cement powder is provided in a mixing syringe packaged in a foil pouch. The foil pouch is then packaged in a plastic tray with a Tyvek lid.	Blister tray packed in a Tyvek-PET/PE pouch

Conclusion:
The Subject Device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in identical materials and are sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Tactoset is as safe, as effective, and performs as well as, or better, than the predicate devices.