August 31, 2021

Anika Therapeutics. Inc.
℅ Wei Zhao
Director, Regulatory Affairs
Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730

Re: K212083
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: July 2, 2021
Received: July 2, 2021

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,

for

Laura C. Rose, 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)*

K212083

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® Injectable Bone Substitute
Manufacturer:	Anika Therapeutics, Inc. 32 Wiggins Avenue Bedford, MA 01730
Contact:	Wei Zhao 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:	August 19, 2021
Classifications:	21 CFR §880.3045, Resorbable calcium salt bone void filler device
Class:	II
Product Codes:	MQV
Primary Predicate:	SCS 17-01 (K173008)
Additional Predicates:	SCS 17-01 (K190956) Cerament Bone Void Filler (K201535) PRO-DENSE (K182823)

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) 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), and water for injection. Tactoset® Injectable Bone Substitute is provided sterile for single use in volumes ranging from 1cc to 4cc and is provided in a kit containing the dry powder component and the liquid component in pre-loaded syringes.

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® Injectable Bone Substitute 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:	SCS 17-01 (K173008)
Additional Predicates:	SCS 17-01 (K190956) Cerament Bone Void Filler (K201535) PRO-DENSE (K182823)

Performance Testing Summary:
Non-clinical verification testing data submitted to demonstrate substantial equivalence included bench performance testing as follows:

- Pull-out testing
- Bone alignment testing

Pyrogenicity and bacterial endotoxin testing were performed using methods described in USP 39-NF 34 <151> and USP 39-NF 34 <85>, and results were below the limits set by the acceptance criteria.

Substantial Equivalence:
The subject device is identical to the SCS 17-01 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. 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, primary predicate device, and additional predicate device all have indications for use in the extremities and pelvis. The subject device and the predicate devices are provided sterile for single-patient, single-use in similar ranges of graft volumes.

No animal performance testing or clinical data are included in this submission.

Overall, Tactoset® Injectable Bone Substitute has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates identical materials,
- has identical manufacturing process,
- has identical packaging and is sterilized using the same materials and processes.

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 similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Tactoset® Injectable Bone Substitute is as safe, as effective, and performs as well as, or better, than the predicate devices.