January 30, 2020

Anika Therapeutics, Inc.
Mira Leiwant
Vice President of Regulatory Affairs, Clinical Affairs and Quality
32 Wiggins Avenue
Bedford, Massachusetts 01730

Re: K190956
Trade/Device Name: SCS 17-01
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: December 20, 2019
Received: January 2, 2020

Dear Mira Leiwant:

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,

Laura C. Rose, 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: *0613012020*
See *PRA Statement below.*

510(k) Number *(if known)*
K190956

Device Name
SCS 17-01

Indications for Use *(Describe)*

SCS 17-01 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.

Type of Use *(Select one or both, as applicable)*

[X] 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

Manufacturer:	Anika Therapeutics, Inc. 32 Wiggins Avenue Bedford, MA 01730 Phone: 781.457.9237
Contact:	Mira Leiwant Vice President, Regulatory Affairs, Clinical Affairs, and Quality Anika Therapeutics, Inc. Phone: 781.457.9204
Date Prepared:	January 29, 2020
Device Trade Name:	SCS 17-01
Device Common Name:	Bone Void Filler
Classification:	21 CFR §888.3045, Resorbable calcium salt bone void filler device
Product Codes:	MQV
Indications for Use:	SCS 17-01 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.

Device Description: The purpose of this submission is to update the current SCS 17-01 bone void filler device to modify the handling properties. The SCS 17-01 product is a synthetic, injectable, settable osteoconductive calcium phosphate bone graft substitute material. SCS 17-01 is composed of a dry powder and an aqueous solution (supplied in separate sterile, pre-loaded syringes) that must be mixed intra-operatively to form a cohesive paste prior to implantation using the supplied mixing system. The dry powder is composed of the alpha phase of tricalcium phosphate (αTCP) [Ca3(PO4)2], calcium carbonate [CaCO3] and monocalcium phosphate [Ca(H2PO4)2]. The aqueous component is composed of water for injection, sodium phosphate dibasic [Na2HPO4], citric acid [C6H8O7] and hyaluronic acid (HA). Upon mixing the cement powder and the setting solution at body temperature, a dissolution and reprecipitation reaction occurs resulting in the precipitation of a poorly crystalline hydroxyapatite. During the healing process, the bone void filler resorbs and is replaced with new bone growth. SCS 17-01 is provided sterile for single use in volumes ranging from 1cc to 4cc.

Predicate Devices: The SCS 17-01 is substantially equivalent to the primary predicate device, SCS 17-01 (K173008), with respect to intended use, indications, design, materials, and performance. The material composition of the dry and aqueous component of the final product is equivalent to that of the predicate. The proposed bone void filler is a modification of the dry powder component of the predicate bone void filler, SCS 17-01 (K173008). The modifications made to the predicate product include the following: increased the dry powder weight from 4g to 5g to modify the handling properties, the notch in the mixing syringe close to the mixing unit was removed by the contract manufacturer, and the addition of four 1cc syringes from Becton Dickinson.

In addition, Stryker Hydroset (K161447) was referenced due to the original SCS 17-01 510(k) claiming equivalence to this device.

Substantial Equivalence:

Anika completed various bench tests to assess the performance of the proposed SCS 17-01 in comparison to the predicate, SCS 17-01 (K173008). Non-clinical testing data submitted to demonstrate substantial equivalence included chemical characterization, physical characterization, and in vivo (animal) performance. All benchtop non-clinical testing was performed in accordance with the FDA guidance *"Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device."* Performance testing assessed the working time, setting time, reaction temperature, changes in pH, calcium dissolution, and dimensional stability and compressive strength. Additionally, the consensus standards ASTM C414-03, ASTM F451-16, ASTM E70-07, ASTM F1926-145, ASTM C39, and ASTM D1204-14 were utilized for developing testing methods for the setting time, reaction temperature, changes in pH, calcium dissolution, dimensional stability, and compressive strength tests, respectively.

With regards to chemical characterization, since there were no changes in materials or purity specifications, powder x-ray diffraction and Fourier transform infrared spectroscopy (XRD/FTIR) were not required for the individual components of the dry powder phase of the subject device. Per elemental analysis, levels of heavy metals are within an acceptable range and are equivalent to the predicate formula.

Physical characterization of the subject device included: device mass, volume and density by gas displacement pycnometry, device porosity by mercury intrusion porosimetry, particle size determination (dry component) and surface microstructure by scanning electron microscopy (SEM).

The materials of the proposed SCS 17-01 bone void filler are equivalent to the materials used in the predicate bone void filler, SCS 17-01 (K173008). No changes have been made to manufacturing or sterilization. These materials have a long history of successful orthopedic use and well-established biocompatibility. Because the materials are equivalent, and

the final reaction product is the same, biocompatibility testing was not repeated.

The radiographic, histologic, histomorphometric, and mechanical performance of the subject device were compared to that of the primary predicate device, SCS 17-01 (K173008), in a New Zealand (NZ) White Rabbit distal femoral condyle critical-sized defect model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the primary predicate device.

Pyrogenicity testing was performed in accordance with the USP 151 (Rabbit Test) and results were below the limits set by the acceptance criteria in USP 161. Endotoxin testing was performed in accordance with USP 85. These standards are all FDA-recognized consensus standards.

All results from the performance testing and material characterization analyses (Section 6) demonstrate that the additional dry powder within the dry powder vial component does not introduce any safety concerns or negatively impact performance.