December 26, 2017

Anika Therapeutics, Inc.
Steven Chartier
Vice President, Regulatory and Clinical Affairs
32 Wiggins Avenue
Bedford, Massachusetts 01730

Re: K173008
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: November 28, 2017
Received: November 28, 2017

Dear Mr. Chartier:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173008

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)*

☒ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Device Trade Name: SCS 17-01

Manufacturer: Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730

Contact: Steven Chartier
Vice President of Regulatory and Clinical Affairs
Phone: 781-457-9000

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Date Prepared: September 27, 2017

Classifications: 21 CFR §880.3045, Resorbable calcium salt bone void filler device

Class: II

Product Codes: MQV

Primary Predicate: Stryker HydroSet (K161447)

Additional Predicate: Globus Medical KINEX Bioactive (K130392)

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:
SCS 17-01 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. SCS 17-01 is provided sterile for single use in volumes ranging from 1.5cc 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 submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, SCS 17-01 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: Stryker HydroSet ™ (K161447)
Additional Predicate: Globus Medical KINEX® Bioactive (K130392)

Performance Testing Summary:
Pre-clinical testing data submitted, referenced to or relied upon to demonstrate substantial equivalence includes chemical composition, physical properties, biocompatibility, and performance characteristics.

Non-clinical testing data submitted to demonstrate substantial equivalence included chemical characterization, physical characterization, sterilization validation, shelf life validation, biocompatibility, and in vivo (animal) performance.

Chemical characterization of the subject device included identification and quantification of crystalline and non-crystalline components using powder x-ray diffraction (PXRD) and Fourier transform infrared spectroscopy (FTIR), and elemental analysis (including heavy metal content) using ion coupled plasmas mass spectroscopy (ICP-MS). Calcium dissolution was performed for the subject device and the primary predicate device, HydroSet. Chemical characterization was performed using methods described in ASTM F1185 and ASTM F1926/F1926M.

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

Biocompatibility testing was performed using methods described in AAMI/ANSI/ISO 10993-1, AAMI/ANSI/ISO10993-5, ISO 10993-10, ISO 10993-11, and ISO 10993-12. Pyrogenicity and bacterial endotoxin testing were performed using methods described in USP 39-NF 34 <151> and USP 39-NF 34 <85>.

Sterilization validation, and product shelf life testing were performed using methods described in AAMI/ANSI/ISO 11137-1, AAMI/ANSI/ISO 11137-2, ASTM F1140/F1140M, and ASTM F2096.

Animal studies were performed to demonstrate substantial equivalence and included determination of radiographic, histologic and histomorphometric characteristics of the subject device and the primary predicate device in a rabbit distal femoral condyle critical-sized defect model. The study time points included baseline (time 0), 6 weeks, and 12 weeks. The baseline (time 0) animals provided information on the initial amount of material implanted to fill the defects. Empty (unfilled) defects (negative control) and defects filled with autograft (positive control) were evaluated at 6 weeks and 12 weeks. Evaluation endpoints included radiography, micro-computed tomography (micro-CT) imaging, decalcified histologic evaluation, histomorphometric analysis, and mechanical testing. Histology sections also were graded according to AAMI/ANSI/ISO 10993-6 (Annex E).

Substantial Equivalence:
The subject device shows substantial equivalence in animal model performance testing, physical form, and material composition to the predicate devices (same mineral components and similar resorbable polymer binding agent). The subject device and the Hydroset (primary predicate device) both incorporate injectable, settable calcium phosphate materials (containing citric acid and a resorbable polymer (Polyvinylpyrrolidone or HA)).

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 (HydroSet), and additional predicate device (KINEX Bioactive) 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.

The radiographic, histologic, histomorphometric, and mechanical performance of the subject device were compared to that of the primary predicate device, HydroSet , in a 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.

No clinical data are included in this submission.

Overall, SCS 17-01 has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar 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. SCS 17-01 is as safe, as effective, and performs as well as, or better, than the predicate devices.