July 29, 2022

Subchondral Solutions, Inc.
Michael Kolber
Consultant, Regulatory Affairs
7146 Edinger Ave. Suite A
Huntington Beach, California 92647

Re: K220901
Trade/Device Name: S-Core® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: May 2, 2022
Received: May 5, 2022

Dear Michael Kolber:

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)*
K220901

Device Name
S-Core® Implant System

Indications for Use *(Describe)*
The S-Core® Implant System (6.0 mm - 10.0 mm diameter) is intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.
Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.
Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.
Hip: Capsular repair, acetabular labral repair, gluteus medius repair.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220901

Device Name
S-Core® Implant System

Indications for Use *(Describe)*
The S-Core® Implant System consists of screws and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for the size of device. These large and small bones may include the following:

Fixation of small bone fragments, such as apical fragments (patellar rim, navicular), minimally invasive reconstruction of fractures and joints, adjuvant for osteosynthesis in complex joint fractures, multifragment joint fractures, simple metaphyseal fractures, fractures of the wrist, ankle, elbow, and shoulder, condylar fractures, osteochrondritis dissecans, osteochondral fixation, fractures, and fragments (talar, vault, femoral condyle), intra-articular fractures, ligament avulsion injuries, ligament fixation, other small fragments, cancellous bone fragments (talus) or fractures, small joint fusion, areas where accurate screw placement is vital, metatarsal and phalangeal osteotomies, fractures of the tarsals, metatarsals and other fractures of the foot, avulsion fractures and fractures of metatarsal V, tarso-metatarsal and metatarso-phalangeal arthrodesis, fractures of small joints, such as: ankle fractures, navicular fractures, fractures of the fibula, malleolus, and calcaneus, distal tibia and pilon fractures, acetabular fractures, tarsal fusions, calcaneal and talar fractures, subtalar arthrodesis, ankle arthrodesis, other fractures of the pelvic ring, fractures of the femoral head and neck, supracondylar femoral fracture, slipped capital femoral epiphyses, an adjunct to DHIS in basilar neck fractures, intercondylar femur fractures, intracapsular fractures of the hip, fractures of the distal femur and proximal tibia, patellar fractures, tibial plateau fractures, small fragments of the hand and wrist, fractures of the carpals and metacarpals, carpal and metacarpal arthrodesis, scaphoid fracture and other fractures of the hand, phalangeal and interphalangeal fractures, fractures of the ulna and radius, radial head fractures, fractures of the olecranon and distal humerus, humeral head fractures, ligament fixation at the proximal humerus, glenoid fractures.

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)

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510(k) Summary

510(k) Number: K220901

Submitter Name and Address

Name: Subchondral Solutions, Inc.
Contact: Michael Kolber
Consultant, Regulatory Affairs
Address: 7146 Edinger Ave. Suite A, Huntington Beach, CA 92647
Telephone: 408-505-6626
Date Prepared: July 27, 2022

General Device Information

Product Name: S-Core® Implant System
Common Name: Suture Anchor and Bone Screw
Classification: 21CFR888.3040, Smooth or threaded bone fixation fastener
Device Class Class II
Product Code: MBI, HWC

Predicate Devices

Primary Predicate: Arthrex Corkscrew Suture Anchor, K143745
Additional Predicates: Subchondral Solutions, Inc. S4 Screw System™, K191995
Subchondral Solutions, Inc. S4 Screw System™, K162171

Device Description

The S-Core® Implants are titanium screws that are threaded, headless, cannulated devices offered in diameters ranging from 4mm to 10mm. Each diameter size offers three length options; the shortest being 7mm for the 4mm diameter screw to the longest at 14mm for the 10mm diameter screw. Each screw body incorporates 0.8mm fenestrations on the screw head surface and in a helical pattern within the thread pitch. All screws are offered with the option of an hydroxyapatite (HA) coating. The system also includes stainless steel screw instruments for implantation.

The S-Core® Implant System may be used as a stand-alone screw for the fixation of fracture, fusion, and osteotomies. The S-Core Implant System may also be used with the S-Fibre Suture when used as a suture anchor for the attachment of soft tissue to bone.

The S-Fibre Suture is a non-absorbable, sterile, surgical suture composed of high molecular weight polyethylene (UHMWPE). It is available in white, size 3-0, meeting USP requirements except for oversize diameter. The S-Fibre Suture was originally cleared as the Force Fiber® Polyethylene Non-Absorbable Suture (K063778).

The S-Core® Implant suture anchor includes the S-Fibre Suture (prepackaged) with the titanium screw.

Intended Use (Indications)

The S-Core® Implant System consists of screws and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for the size of device. These large and small bones may include the following:

Fixation of small bone fragments, such as apical fragments (patellar rim, navicular), minimally invasive reconstruction of fractures and joints, adjuvant for osteosynthesis in complex joint fractures, multifragment joint fractures, simple metaphyseal fractures, fractures of the wrist, ankle, elbow, and shoulder, condylar fractures, osteochrondritis dissecans, osteochondral fixation, fractures, and fragments (talar, vault, femoral condyle), intra-articular fractures, ligament avulsion injuries, ligament fixation, other small fragments, cancellous bone fragments (talus) or fractures, small joint fusion, areas where accurate screw placement is vital, metatarsal and phalangeal osteotomies, fractures of the tarsals, metatarsals and other fractures of the foot, avulsion fractures and fractures of metatarsal V, tarso-metatarsal and metatarso-phalangeal arthrodesis, fractures of small joints, such as: ankle fractures, navicular fractures, fractures of the fibula, malleolus, and calcaneus, distal tibia and pilon fractures, acetabular fractures, tarsal fusions, calcaneal and talar fractures, subtalar arthrodesis, ankle arthrodesis, other fractures of the pelvic ring, fractures of the femoral head and neck, supracondylar femoral fracture, slipped capital femoral epiphyses, an adjunct to DHIS in basilar neck fractures, intercondylar femur fractures, intracapsular fractures of the hip, fractures of the distal femur and proximal tibia, patellar fractures, tibial plateau fractures, small fragments of the hand and wrist, fractures of the carpals and metacarpals, carpal and metacarpal arthrodesis, scaphoid fracture and other fractures of the hand, phalangeal and interphalangeal fractures, fractures of the ulna and radius, radial head fractures, fractures of the olecranon and distal humerus, humeral head fractures, ligament fixation at the proximal humerus, glenoid fractures.

The S-Core® Implant System (6.0 mm – 10.0 mm diameter) is intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures:

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Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.
Hip: Capsular repair, acetabular labral repair, gluteus medius repair.

Comparison of Technology

The purpose of this submission is to simplify the Indications for Use of the S-Core® Implant system when used as a standalone screw, and inclusion of suture with the screw for the S-Core® Implant System when used as a suture anchor.

The S-Core® Implant System is substantially equivalent to the predicate devices, in which the basic design and intended uses are the same. Any differences between the S-Core® Implant System described in this submission and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

The submitted test data demonstrates that the proposed device is substantially equivalent to the predicates.

The S-Core® Implant System use as a suture anchor is substantially equivalent to the Arthrex Corkscrew (K143745) with regard to the indications for use, technological characteristics, and the summary of data submitted.

The S-Core® Implant System intended use for fixation or fractures, fusion and osteotomies is a combination of the indications previously included in the S4 Screw System (K191995, K162171). Of note is that the primary predicate for the S4 Screw System (K191995) was the S4 Screw System (K162171).

Summary of Non-Clinical Performance Testing

Bench Test

Mechanical testing of the S-Core® Implant System was previously performed and reported in K191995. These previously reported tests included Torsional Properties, Insertion and Removal Torque, and Pullout Strength. Fatigue testing was also performed on the S-Core® Implant suture anchors, constructed with HA coated screws, and compared to the Arthrex Corkscrew previously cleared in K143745 in order to evaluate the device when used as an anchor. The testing demonstrated that the device is resistant to failure of the anchor due to suture fray or fatigue failure of the anchor component.

Bacterial endotoxin testing was performed and the implants were found to meet the specified pyrogenicity limit.

Statement of Equivalence

Based on similarities in indications for use and technological characteristics, we believe the S-Core® Implant System is substantially equivalent to the predicate devices.