April 18, 2020

Subchondral Solutions, Inc.
Michael Kolber
Consultant
147 Hillbrook Drive
Los Gatos, California 95032

Re: K191995
Trade/Device Name: S4 Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 19, 2019
Received: July 26, 2019

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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191995

Device Name
S4 Screw System™

Indications for Use *(Describe)*
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, Ostero-Chondral Fractures, Ligament avulsion injuries, Ligament fixation, Other small fragment, cancellous bone 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; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis, Ankle 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. Other fractures of the pelvic ring; Fractures of the femoral head and neck, Supracondylar femoral fractures, 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, Carnal 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number K191995

Submitter Name and Address

Name: Subchondral Solutions, Inc.
Contact: Michael Kolber
Consultant, Regulatory Affairs
Address: 147 Hillbrook Drive
Los Gatos, CA 95032
Telephone: 408-505-6626
Date Prepared: April 16, 2020

General Device Information

Product Name: S4 Screw System™
Common Name: Bone Screw System
Classification: 21CFR888.3040, Smooth or threaded bone fixation fastener
Device Class Class II
Product Code: HWC

Predicate Devices

Primary Predicate: Subchondral Solutions, Inc. S4 Screw System (K162171)
Additional Predicates: Acumed Cannulated Screw System (K123890)
Medacta International M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System (K171595)
Reference Devices: Newclip Technics (K160617)
Tyber Medical, Trauma Screw (K153575)

Device Description

The S4 Screw System is collection of cannulated, headless screws having fenestrations on the head and within the thread pitch.

Intended Use (Indications)

The S4 Screw System consists of screws and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for size of device. These large and small bones may include the following:

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, Ostero-Chondral Fractures, Ligament avulsion injuries, Ligament fixation, Other small fragment, cancellous bone 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; Tarsal Fusions; Calcaneal and talar fractures, Subtalar arthrodesis, Ankle 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. Other fractures of the pelvic ring; Fractures of the femoral head and neck, Supracondylar femoral fractures, 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, Carnal 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.

Comparison of Technology
The S4 Screw System (subject device) has a modified intended use compared to the predicate device, but identical to the Acumed Cannulated Screw System.

Also, additional sizes have been added (reference devices Newclip Technics, K160617 and Tyler Medical, K153575), as well as the optional addition of hydroxyapatite (HA) coating (additional predicate device Medacta Intl., K171595). The purpose of the additional sizes is to enable to repair larger bones, as appropriate for the size of the device. The purpose of the HA coating is to improve bone growth.

Summary of Non-Clinical Performance Testing
Bench Test
Mechanical testing of the S4 Screw System was performed, per ASTM F543. The selected tests include Torsional Properties, Insertion and Removal Torque, and Pullout Strength. In addition, information about the hydroxyapatite-coating is referenced in the Master File.

Packaging and Sterilization
A packaging performance study was completed to validate packaging performance. Also, a sterilization validation study was also completed.

Risk Assessment/Analysis
A Failure Modes and Effects Analysis (FMEA) was used to assess changes made to the subject S4 Screw System compared to the predicate S4 Screw System with regard to the modified intended use, as well as the additional sizes and HA coating. The analysis determined that the modifications resulted in an acceptable low risk category.

Referenced Standards

ASTM F136-13 -	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F899-12b -	Standard Specification for Stainless Steel for Surgical Instruments.
ASTM F1185-03 -	Standard Specification for Composition of Hydroxyapatite for Surgical Implants

ASTM F543-17 -	Standard Specification and Test Methods for Metallic Medical Bone Screws
ISO 11137-1:2017 -	Sterilization of health care products – Radiation – Part 1: Requirement for device validation and routine control of a sterilization process for medical devices

Statement of Equivalence

Based on similarities in indications for use and technological characteristics, as well as non-clinical performance testing, we believe the S4 Screw System is substantially equivalent to the predicate devices.