Subchondral Solutions
% Karen E. Warden, Ph.D.
President
Backroads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K162171
  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: August 7, 2017
  Received: August 8, 2017

Dear Dr. Warden:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
S4 Screw System™

The S4 Screw System™ is indicated for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments, appropriate for the size of the device which may include the following: simple metaphyseal fractures; condylar fractures; osteochondritis dissecans; areas where accurate screw placement is vital; apical fragments (patellar rim, navicular); cancellous fragments (talus); osteochondral fragments (talar vault, femoral condyle); intra-articular fractures and osteochondral fixation and 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
510(k) Summary

Date: 7 August 2017
Sponsor: Subchondral Solutions, Inc.
147 Hillbrook Drive
Los Gatos, CA 95032
Office: 408.891.9604
Contact Person: Sheryl McCoy, Chief Financial Officer and VP of Administration
510(k) Contact: Karen E. Warden, PhD
BackRoads Consulting Inc.
PO Box 566
Chesterland, OH 44026
Office: 440.729.8457

Proposed Trade Name: S4 Screw System™
Common Name: Bone screw
Device Classification: Class II
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation: 888.3040
Device Product Codes: HWC
Device Description: The S4 Screw System™ is collection of cannulated, headless screws having fenestrations on the head and within the thread pitch.

Indications for Use: The S4 Screw System™ is indicated for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments, appropriate for the size of the device which may include the following: simple metaphyseal fractures; condylar fractures; osteochondritis dissecans; areas where accurate screw placement is vital; apical fragments (patellar rim, navicular); cancellous fragments (talus); osteochondral fragments (talar vault, femoral condyle); intra-articular fractures and osteochondral fixation and fractures.

Materials: The S4 Screw System™ components are manufactured from titanium alloy (Ti-6Al-4V per ASTM F136).

Primary Predicate: Acumed Cannulated Screw System (Acumed LLC. – K123890)
Additional Predicate: Arthrex Compression FT Screws (Arthrex, Inc. – K132217)

Performance Data: Mechanical testing of the worst case S4 Screw System™ and a predicate component included torsion, insertion and pushout according to ASTM F543. The mechanical test results demonstrated that S4 Screw System™ performance is substantially equivalent to the predicate devices. In addition, bacterial endotoxin testing was performed and the implants were found to meet the specified pyrogenicity limit.

Technological Characteristics: The S4 Screw System™ possesses similar technological characteristics as one or more of the predicate devices. These include:
  - performance (as described above),
  - basic design (cannulated, headless screws) and
  - implant materials (titanium alloy).

Differences between the subject and predicate devices did not raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the S4 Screw System™ is similar to previously cleared devices.

Conclusion: The S4 Screw System™ possesses the same intended use and similar technological characteristics as the predicate devices. Therefore the S4 Screw System™ is substantially equivalent for its intended use.