DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 5, 2017

Sicage LLC
% Karen E. Warden, Ph.D.
President
BackRoads Consulting Inc.
P.O. Box 566
Chesterland, Ohio 44026-0566

Re: K170475
Trade/Device Name: SICAGE™ System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: February 14, 2017
Received: February 16, 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,

Mark N. Melkerson -S

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

Enclosure

510(k) Summary

Date:	14 February 2017
Sponsor:	Sicage LLC 6709 S. Minnesota Ave, Suite 206 Sioux Falls, SD 57108
Sponsor Contact:	Kristi Vondra, VP of Operations
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Proposed Trade Name:	SICAGE™ System
Common Name:	Cannulated bone screw
Regulatory Class:	Class II
Regulation Name, Regulation Number, Product Codes:	Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040, OUR
Device Description:	SICAGE is a fully threaded bone screw offered in a single diameter and various lengths to accommodate variability in patient anatomy. SICAGE is sold sterile. The SICAGE System includes implants and instruments for implantation.
Indications for Use:	SICAGE is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.
Materials:	The SICAGE bone screws are manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136).
Primary Predicate:	Synthes 6.5mm Cannulated Screw (Synthes (USA) – K021932)
Additional Predicate:	Silex Sacroiliac Joint Fusion System (X-Spine Systems – K123702)
Performance Data:	Mechanical testing of worst case SICAGE System screws included torsion and pullout per ASTM F543 and static and dynamic bending per ASTM F2193. The mechanical test results demonstrated that SICAGE System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The SICAGE System possesses the same technological characteristics as one or more of the predicate devices. These include: • intended use (as described above) • basic design (threaded bone screw), • material (titanium alloy) and • sizes (dimensions are comparable to those offered by the predicate systems) The fundamental scientific technology of the SICAGE System is the same as previously cleared devices.
Conclusion:	The SICAGE System possesses the same intended use and technological characteristics as the predicate devices. Therefore SICAGE System is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K170475

Device Name
SICAGE™ System

Indications for Use *(Describe)*

SICAGE is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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