DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Radicle Orthopaedics, Inc.
Mr. John Kapitan
CEO
Kapstone Medical LLC
P.O. Box 969
Leicester, North Carolina 28748

Re: K161334
Trade/Device Name: RASL Repair Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 2, 2017
Received: January 3, 2017

Dear Mr. Kapitan:

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 yours,

Mark N. Melkerson -S

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

Enclosure

7. Indications for Use Statement

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 below.

510(k) Number *(if known)*

K161334

Device Name

RASL Repair Kit

Indications for Use *(Describe)*

The RASL Repair Kit is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include acute or chronic, static or dynamic scapholunate instability in the absence of significant capitolunate osteoarthritis, scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

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)

8. 510(k) Summary

Applicant:

Radicle Orthopaedics, Inc.
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New York, NY 10150

Official Correspondent:

Kapstone Medical LLC
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Leicester, NC 28748

Contact Person:
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Date Prepared: January 2, 2017

Common/Usual Name: Bone Screw
Trade Name: RASL Repair Kit
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation Number: 21CFR888.3040
Product Code: HWC
Classification: II
Panel: Orthopedic

Predicate Devices
The Radicle Orthopaedics RASL Repair Kit is substantially equivalent to the following device:

510(k) Number	Device	Manufacturer
K111608	Acumed SLIC Screw Repair System	Acumed
K143165	Herbert/Whipple Bone Screw	Zimmer

Description of the Device
The Radicle Orthopaedics RASL Repair Kit is an implant and instrument system designed to treat scapholunate ligament ("SLIL") ruptures. The RASL Repair Kit implants are made from titanium alloy, Ti-6Al-EV ELI, per ASTM F136. Instruments are made from surgical-grade stainless steel according to ASTM F899. The entire kit is supplied non-sterile. Instruments are meant to be reusable.

Indications for Use

The RASL Repair Kit is intended to provide fixation and anatomically reduce two bones or bone portions. Specifically, these indications include acute or chronic, static or dynamic scapholunate instability in the absence of significant capitolunate osteoarthritis, scapholunate ligament repair, scapholunate reduction, lunotriquetral ligament repair, lunotriquetral reduction, and carpal instability.

Summary of Technical Similarities and Differences

The Radicle Orthopaedics RASL Repair Kit is substantially equivalent to the Acumed SLIC Screw Repair System (K111608) and the Zimmer HBS Screw System (K143165). The devices have the similar "Indications for Use" and product codes, are available by prescription only, have similar sizes offered and are provided non-sterile.

The devices also all include a larger proximal threaded portion and a smaller distal threaded portion.

The RASL device and the HBS device are both made from titanium alloy while the SLIC screw is made from stainless steel.

The key technical difference between the implants is the allowance for angulation and rotation of the distal and proximal portions of the respective implants. The SLIC screw allows for 15 to 22 degrees of toggle angle and freely rotates while the HBS screw is monolithic in nature, allowing for neither rotation or angulation. The RASL screw allows for free rotation while limiting angulation.

Summary of Performance Data

To characterize the strength of the RASL Repair Kit implants and compare to the predicates, the following testing was performed:

- Torsional Testing per ASTM F543
- Insertion/Removal and Axial Pullout Testing per ASTM F543
- Assembly Strength Testing
- Static and Fatigue Bending Testing per ASTM F1264
- Corrosion Testing per ASTM F2129
- Wear Debris Testing per ASTM F1877

Safety & Effectiveness

The Radicle Orthopaedics RASL Repair Kit is substantially equivalent to the predicate devices. The devices have the same Indications for Use, are available by prescription only, have similar sizes offered and are provided non-sterile. In addition, the RASL system performed substantially equivalently to the predicate devices in all testing modes.