F & A Foundation LLC d.b.a. Reign Medical
% Daniel Lanois
Member and Engineer
SurgOp Support LLC
3270 Walton Riverwood Lane SE #4025
Atlanta, Georgia 30339

April 6, 2018

Re: K173775
Trade/Device Name: Clench Compression Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: February 21, 2018
Received: February 27, 2018

Dear Daniel Lanois:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

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)*

K173775

Device Name

Clench Compression Staple

Indications for Use *(Describe)*

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

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.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary** (as required by 21 CFR 807.92)

| | |
|---|---|
| Date Prepared | December, 9, 2017 |
| Manufacturer | F & A Foundation LLC d.b.a. Reign Medical |
| Address | 6303 E 102nd Street<br>Suite 200<br>Tulsa, OK 74137 |
| Telephone | 918-302-9546 |
| Fax | 918-863-8996 |
| Contact Person | Daniel Lanois<br>Member and Engineer |
| Address | SurgOp Support LLC<br>3270 Walton Riverwood Lane SE<br>Unit 4025<br>Atlanta, GA 30339 |
| Telephone | 678-371-3605 |
| Fax | 918-863-8996 |
| Email | daniel@surgopsupport.com |
| Trade Name | Clench® Compression Staple |
| Common Name | Bone Staple |
| Panel Code | Orthopaedic/87 |
| Classification Name | Staple, Fixation, Bone |
| Class | Class II |
| Regulation Number | 21 CFR 888.3030 |
| Product Code | JDR |

| **Name of Predicate Device** | **510(k) #** | **Manufacturer** |
|---|---|---|
| Speed™ | K142292 | BioMedical Enterprises, Incorporated |
| Memodyn Staple | K002695 | Telos Medical Equipment |

| | |
|---|---|
| **Description** | The Clench® Compression Staple is an implant for use in bone fixation and reconstructive surgical procedures for the management of bone fractures. The implant is designed to provide constant compression over a bone fracture site. Implants are made from Nickel-Titanium Alloy per ASTM F2063 and range in size from 7mm to 20mm wide with two equal length legs ranging from 5mm to 20mm long. |
| **Indications and Intended Use** | • Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.<br>• Fixation of proximal tibial metaphysis osteotomy<br>• Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.<br>• Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum. |
| **Technological Characteristics/ Substantial Equivalence** | Documentation was provided to demonstrate that the Subject device, is substantially equivalent to the Predicate. The Subject device is substantially equivalent to the Predicate device in intended use, indications for use, materials, technological characteristics, and labeling. |
| **Performance Data** | Static axial pull-out, Static Four-Point bending, and Dynamic Four-Point bending testing (per ASTM F564-10) confirmed that the Subject device performed as intended. Corrosion Susceptibility testing (per ASTM F2129) confirmed that the Subject device performed as intended. Transformation Temperature testing (per ASTM F2082) confirmed that the Subject device performed as intended. |
| **Conclusion** | Based on the intended use, indications for use, technological characteristics, materials, and comparison to Predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed Predicate devices. |