September 14, 2018

Cable Fix Medical LLC
% Janet Akil
Senior Project Manager I
M Squared Associates, Inc
575 Eighth Avenue, Suite 1212
New York, New York 10018

Re: K173910
Trade/Device Name: Impress SFS System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: August 13, 2018
Received: August 14, 2018

Dear Janet Akil:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mark N. Melkerson -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173910

Device Name
Impress SFS System

Indications for Use *(Describe)*
The Impress SFS System is indicated for general orthopaedic repair procedures. The Impress SFS System is also intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle 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.

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

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510(k) Summary: **K173910**

Sponsor: **Cable Fix Medical LLC**
1050 Getwell Rd. S.
Hernando, MS 386324246

Phone: 901-552-8088

Contact: Carey Bryant

Date Prepared: September 7, 2018

Trade Name: **Impress SFS System**

Common Name: Orthopedic cable system

Classification: 888.3010 Bone fixation cerclage

Product Code: JDQ/Orthopedics, Class II

Predicate Devices: Orthopedic Cable System, Smith & Nephew (K031162)
Kirschner Wires (K-Wires), Steinmann Pins and Orthopedic Cable System, Synthes (K960385, K953777)
TightRope Syndesmosis Device, Arthrex (K043248)

Description of Device:

The Impress SFS System is cable system which includes components such as cables and which are manufactured from stainless steel. These components are used together to address the indications as outlined in the next section. The implantable components in the Impress SFS System are provided sterile as indicated on the outer carton label.

Indications for Use:

The Impress SFS System is indicated for general orthopaedic repair procedures. The Impress SFS System is also intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Technological Characteristics:

The technological characteristics for the Impress SFS System are the same as the characteristics of the predicate devices. The components are manufactured in similar sizes and designs as the predicate devices. In addition, the components Impress SFS System are manufactured from the same materials as the predicate devices.

Mechanical testing (stop strength, washer locking strength and cable strength) confirmed that the device is equivalent to predicate devices and pyrogen testing confirmed that the endotoxin requirements have been met.

Substantial Equivalence

The design features of the Impress SFS System are substantially equivalent to the design features of other predicate devices previously cleared for market. The methods used to establish equivalence are based on the comparison of the intended use, product technical characteristics and performance characteristics (stop strength, washer locking strength and cable strength). All comparisons confirmed that the Impress SFS System is substantially equivalent to the predicate devices. The safety, effectiveness, and performance of the Impress SFS System are adequately supported by the substantial equivalence information, material information and analysis data provided within this Premarket Notification. Therefore, it is concluded that the Impress SFS System is substantially equivalent to the noted predicate devices.

Conclusions

While the Impress SFS System is not identical to the predicate devices, any differences that may exist do not significantly affect device safety and effectiveness. In addition, the differences do not add new or increased risks and complications. Therefore, it is concluded that the Impress SFS System is substantially equivalent to the predicate devices as outlined previously and should not render the subject device NSE.