November 7, 2017

Dallen Medical, Inc.
Al Memmolo
Chief Operating Officer
1046 Calle Recodo, Suite G
San Clemente, California 92673

Re: K171473
Trade/Device Name: Compressyn™ 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: September 29, 2017
Received: October 3, 2017

Dear Al Memmolo:

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)*

K171473

Device Name

Compressyn™ Staple

Indications for Use *(Describe)*

The Compressyn™ Staple is intended for: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy, 3) adjunctive fixation of small bone fragments. These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremity; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in the flat bones such as the pelvis, scapula and sternum.

Type of Use *(Select one or both, as applicable)*

[X] 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 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

GENERAL INFORMATION

APPLICANT:	Dallen Medical, Inc. 1046 Calle Recodo, Suite G San Clemente, CA 92673 (949) 218-0030 (949) 218-0040 Fax
CONTACT PERSON:	Al Memmolo Chief Operating Officer
DATE PREPARED:	September 29, 2017

DEVICE DESCRIPTION:

TRADE NAME:	Compressyn™ Staple
GENERIC/COMMON NAME	Fixation Staple
CLASSIFICATION NAME:	Single/multiple component metallic bone fixation appliances and accessories, CFR 888.3030
PRODUCT CODE:	JDR
DEVICE CLASSIFICATION:	Class II
PREDICATE DEVICES:	Dallen Medical Compressyn Staple, Preloaded Sterile System (K140358) New Deal SA Uni-Clip Staple (K991482)

Product Description:

The Compressyn Staple is a fully integrated system that consists of a stainless steel staple preloaded on a handheld ABS and polycarbonate mechanical delivery device. The staple is offered in 14 sizes with barbs to prevent back out. It is a compression staple fixation device that is placed into two tissue segments using pre-drilled holes to provide stabilized fixation. The Compressyn Staple is provided sterile in a disposable tray with a drill bit, drill guide, placement pins and staple sizing guide.

Indications for Use:
The Compressyn Staple is intended for: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy, 3) adjunctive fixation of small bone fragments. These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremity; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in the flat bones such as the pelvis, scapula and sternum.

Technical Characteristics and Performance Data:
The Compressyn Staple is identical to the predicate and therefore has the same physical and technical characteristics. The Compressyn Staple was tested for staple delivery and compressive force and was shown to be equivalent to the predicate. Testing to ASTM F564-10 was also performed for the Compressyn Staple, Preloaded Sterile System.

Basis for Determination of Substantial Equivalence:
Upon reviewing the documentation provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Compressyn Staple is determined by Dallen Medical to be substantially equivalent to existing legally marketed devices.