K101484

6. 510 (k) Summary

APR - 1 2011

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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 Operations Officer
DATE PREPARED:	March 28, 2011

DEVICE DESCRIPTION:

TRADE NAME:	Compressyn™ Band
GENERIC/COMMON NAME	Cerclage Bone Fixation
CLASSIFICATION NAME	Bone Fixation, Cerclage, CFR 888.3010 (code JDQ)
DEVICE CLASSIFICATION	Class II
PREDICATE DEVICES:	KLS Martin Sternal Talon (K070169) Sternal Band (K930015) Pioneer Sternal Cable System (K993286) Mersilene Polyester Fiber Suture (pre-amendment device) Ethicon Stainless Steel Suture Wire (K931271/ K946173) Synthofil Nonabsorbable PET Surgical Suture (K990088)

Product Description:

The Compressyn™ Band System consists of a stainless steel coupler preloaded with a polyester fiber band. It is a cerclage fixation device that is placed around or through the sternum and locked in place to provide stabilized fixation.

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Indications for Use:

The Compressyn™ Band is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

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Technical Characteristics:

The Compressyn™ Band has similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed with the Compressyn™ Band to assure substantial equivalence to the predicate devices. Comparative testing against predicate devices included the following tests:

- Sternal compression
- Static performance to a 5mm gap
- Static performance to point of failure
- Cyclic performance to a 5mm gap
- Cyclic performance to point of failure
- Cyclic performance to 2000 cycles

The testing demonstrated that the Compressyn™ Band is substantially equivalent to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, the Compressyn™ Band is determined by Dallen Medical, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

APR - 1 2011

Re: K101484
Trade/Device Name: Compressyn™ Band
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: March 23, 2011
Received: March 24, 2011

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101481

Device Name: **Compressyn™ Band**

Indications for Use:

The Compressyn™ Band is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101481

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