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

Austin & Associates, Inc./Telos Medical Equipment
Al Austin
Manager
212 Copperwood Court
Millersville, MD 21108

February 1, 2017

Re: K161587
Trade/Device Name: Memodyn 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: December 30, 2016
Received: January 3, 2017

Dear Mr. Austin:

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

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)*

K161587

Device Name
Memodyn Staple

Indications for Use *(Describe)*
Memodyn Staple is intended for use in bone fixation on osteotomies, arthrodesis and fractures of the small bones of the foot, ankle and hand.

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
[as required by 21 CFR 807.92(c)]

Memodyn Staple
510(k): K161587

DATE PREPARED:	January 27, 2017
APPLICANT	Austin and Associates, Inc./Telos Medical Equipment 212 Copperwood Court Millersville, MD 21108 Phone: 410-903-9038 Fax: 410-544-3547 Email: telosusa@aol.com
OFFICIAL CORRESPONDENT	Al Austin, Manager 212 Copperwood Court Millersville, MD 21108 Phone: 410-903-9038 Fax: 410-544-3547 Email: telosusa@aol.com
ADDITIONAL CORRESPONDENT	Cheryl Wagoner, Consultant Wagoner Consulting LLC PO Box 15729 Wilmington, NC 28408 Phone: 910-386-9019 Email: cheryl@wagonerconsultingllc.com
TRADE NAME:	Memodyn Staple
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §888.3030
COMMON NAME:	Staple, Fixation, Bone
CLASSIFICATION NAME:	Single/multiple component metallic bone fixation appliances and accessories
PRODUCT CODE	JDR
PREDICATE DEVICE:	Memodyn Staple (K002695)
REFERENCE DEVICE	Vilex Staple (K112837)

INTENDED USE/INDICATIONS FOR USE

Memodyn Staple is intended for use in bone fixation on osteotomies, arthrodesis and fractures of the small bones of the foot, ankle and hand.

DESCRIPTION:

Memodyn Staple is a nitinol alloy ASTM F2063-12 memory staple that comes in sizes ranging from 8mm to 20mm, and is used for bone fixation on osteotomies, arthrodesis and fractures of the small bones of the foot, ankle and hand.

COMPARISON WITH PREDICATE DEVICES:

The Memodyn Staple is substantially equivalent in design, materials, intended use, indications for use, principles of operations and technological characteristics as the predicate Memodyn Staple (K002695).

The Memodyn Staple (Subject device) is a memory staple that is made of the same Nitinol alloy material as the predicate. The implant is single use which is the same as the predicate. The staple sizes are the same as the predicate but have barbs on the staple legs. There are differences in the packaging, provided non sterile. The accessory components are sterilized in the same manner as the predicate device. The risk analysis raises no new issues relative to safety or effectiveness.

The intended use/indications between the Subject Device and its predicate are identical.

Name of Device	**Memodyn Staple (Subject Device)**	**Memodyn Staple (Predicate)**
510(k)	Current Application	K002695
Indications for Use	*Memodyn Staple is intended for use in bone fixation on osteotomies, arthrodesis and fractures of the small bones of the foot, ankle and hand.*	*Memodyn Staple is intended for use in bone fixation on osteotomies, arthrodesis and fractures of the small bones of the foot, ankle and hand.*
Sterilization	Non-Sterile to be steam sterilized by user facility	Gamma irradiation (ASTM 11137-1, 11137-2)
Shelf Life	N/A	10 years
Overall Length	8 – 20 mm	8 – 20 mm
Staple Bridge/Top Width	8 - 20 mm	8 - 20 mm
OD of staple	1.7mm	1.7mm

NON CLINICAL TESTING / PERFORMANCE DATA:
The verification and validation testing of the Memodyn Staple (Subject device) fixation implant included staple static four point bending, dynamic four point bending (fatigue) and elastic compression distribution of the legs per ASTM F2063. Pullout strength was demonstrated through scientific rationale.

BIOCOMPATIBILITY:
The Subject device was compared to the predicate. All of materials used for Subject device are biocompatible and identical to the predicate and are manufactured in an identical manner. The change in sterilization method has no impact upon the biocompatibility of the material.

CONCLUSION:
The Subject device has same intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, shelf life and operating principles as the predicate devices. Performance data demonstrates that the device performs as well as the predicate device. Therefore, the Memodyn Staple is substantially equivalent to the predicate device.