



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

July 9, 2015

CONMED Corporation  
Ms. Nyrobia Freeman  
Regulatory Affairs Specialist  
525 French Road  
Utica, New York 11502

Re: K151037

Trade/Device Name: GraftMax™ Button, ALB with Cradle and GraftMax™ Button, BTB with Cradle  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Class: Class II  
Product Code: MBI  
Dated: June 5, 2015  
Received: June 10, 2015

Dear Ms. Freeman:

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" (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 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,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151037

Device Name

GraftMax™ Button, ALB with Cradle  
GraftMax™ Button, BTB with Cradle

Indications for Use (Describe)

The device is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts or bone tendon grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, lateral collateral ligament, distal biceps tendon rupture, and separations due to coracoclavicular ligament disruptions.

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"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

I. SUBMITTER

CONMED Corporation  
525 French Road  
Utica, New York  
Phone: 727-399-5416  
Fax: 727-399-5264  
Date Prepared: June 26, 2015

Company Contact

Nyrobia Freeman  
Regulatory Affairs Specialist  
Telephone (727) 399-5416  
Fax (727) 399-5264

II. DEVICE

Trade of Device: GraftMax™ Button, ALB (Adjustable Loop Button) with Cradle and GraftMax™ Button, BTB (Bone-Tendon-Bone) with Cradle  
Common Name: Titanium Fixation Device  
Classification Name: Fastener, Fixation, Non-degradable, Soft-Tissue  
Regulatory Class: Class II  
Product Codes: MBI  
Regulation: 21 CFR Part 888. 3040

III. PREDICATE DEVICE

Device Name: GraftMax™ Button, ALB (Adjustable Loop Button) and GraftMax™ Button, BTB (Bone-Tendon-Bone)  
Company Name: CONMED Corporation  
510(k) #: K070780

IV. DEVICE DESCRIPTION

The GraftMax™ Button, ALB (Adjustable Loop Button) with Button Cradle and GraftMax™ Button, BTB (Bone-Tendon-Bone) with Button Cradle are sterile, single use devices. The button and cradle used together measure 21mm in length and 6mm in width. The devices are oval shaped and manufactured of titanium alloy. The devices are designed with five (5) holes that sutures can be threaded through.



V. INDICATIONS FOR USE

The device is intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or reconstruction of a ligament using soft tissue grafts or bone tendon grafts. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, lateral collateral ligament, distal biceps tendon rupture, and separations due to coracoclavicular ligament disruptions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The GraftMax™ Button ALB with Cradle, and the GraftMax™ Button BTB, with Cradle are identical in intended use and principles of operation to the predicate device with exceptions of dimensions, sterilization and packaging.

	Proposed Device	Predicate Device
Dimensions	21mm x 6mm	14mm x 4.5mm
Sterilization	Implant- Gamma Cradle- EtO	Implant – Gamma
Packaging	Implant - Sterile, single use package Cradle – Sterile, single use package , packaged separately	Implant- Sterile, single use package

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Completed testing includes the following:

- Reliability
- Packaging
- Ultimate Fixation Strength
- Cyclic
- Sterilization
- Verification Testing
- Transportation
- Biocompatibility
- User Validation
- Shelf-life

## VIII. CONCLUSION

The GraftMax™ Button ALB with Cradle, and the GraftMax™ Button BTB, with Cradle are substantially equivalent in design, manufacturing materials, intended use, principles of operation to the predicate GraftMax™ Button ALB, and GraftMax™ Button, BTB and raises no new issues of safety or effectiveness.