K070780

510(k) Summary
ConMed Linvatec XO Button™
July 28, 2007

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5. 510(k) SUMMARY

ConMed Linvatec XO Button™

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number .

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Elizabeth M. Paul
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name:	*Conmed Linvatec XO Button™*
Common Name:	Titanium Fixation Device
Classification Name:	888.3040 – Fastener, Fixation, Non-degradable, soft-tissue
	888.3030 – Plate, Fixation, Bone
	888.5000 – Suture, non-absorbable, synthetic, polyethylene
	888.3030– Washer, Bolt Nut
Proposed Class/Device:	Class II
Product Code:	MBI, HRS, GAT, HTN

510(k) Summary
ConMed Linvatec XO Button™
July 28, 2007

D. Predicate/Legally Marketed Devices

The predicate/legally marketed devices for the XO Button™ are:

Device name:	Endobutton Continuous Loop
Company name:	Smith and Nephew
510(k) #:	K980155
Device name:	RetroButton
Company name:	Arthrex
510(k) #:	K062747
Device name:	Tightrope Acromioclavicular (AC) Device
Company name:	Arthrex
510(k) #:	K052776

E. Device Description

The ConMed Linvatec XO Button™ is a sterile, single use, implant for fixation of soft tissue to bone in orthopedic procedures. The XO Button™ is designed with both a continuous loop for fixation of soft tissue to bone and without a continuous loop. The body of the implant is composed of titanium (TI-6AL-4V-ELI) with the following dimensions: length from12 to 18mm and width 4.5 ± .1mm. The continuous loop ranges in size from 10 to 60mm.

F. Intended Use – XO Button with Continuous Loop

The XO Button with continuos loop 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. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.

Intended Use – XO Button without Continuous Loop

The XO Button with continuos loop 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.

G. Substantial Equivalence

The XO Button™ is substantially equivalent in scientific technology, design and intended use to the Smith and Nephew Endobutton, the Arthrex RetroButton and the Arthrex Tightrope Acromioclavicular (AC) Device. The Endobutton was cleared by FDA under 510(k) K980155. The RetroButton was cleared by FDA under 510(k) K062747 and the Tightrope Acromioclavicular (AC) Device under 510(k) K052776.

The XO Button™, the EndoButton Continuous Loop, the RetroButton have similar designs. All are used in fixating soft tissue ligaments. The components are similar. The suture lengths are similar. All are single-use devices. The XO Button™ and the TightRope Acromioclavicular (AC) Device have similar indications for use and design except that the XO Button™ involves only one sized metal button.

Any differences between the XO Button™ and the identified predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec
% Ms. Elizabeth M. Paul
Manager, Regulatory Affairs
13111 Concept Boulevard
Largo, FL 33773-4908

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Re: K070780
Trade/Device Name: Conmed Linvatec XO Button™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, GAT
Dated: August 6, 2007
Received: August 9, 2007

Dear Ms. Paul:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): _K070780_____

Device Name: __ConMed Linvatec XO Button™ without Continuous Loop____

Indications for Use:

The XO Button without continuos loop 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): _K070780_____

Device Name: __ConMed Linvatec XO Button™ with Continuous Loop____

Indications for Use:

The XO Button with continuos loop 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. Examples of such procedures include anterior cruciate ligament, posterior cruciate ligament, medial collateral ligament, and lateral collateral ligament.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070780