510(k) SUMMARY

ConMed Linvatec Presto™, Preloaded with one or two #2 Hi-Fi® Sutures

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 K092898.

A. Submitter

OCT 1 7 2009

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

B. Company Contact

Lorna Linville
Regulatory Affairs Manager
Phone: 727-399-5396
Fax: 727-399-5264

C. Device Name

Trade Name:	ConMed Linvatec Presto, Preloaded with one or two #2 Hi-Fi® Sutures
Common Name:	Bioabsorbable suture anchor
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Proposed Class/Device:	Class II
Product Code:	MAI
Regulation:	21 CFR Part 888.3030

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec Bio Mini-Revo Suture Anchor
Company Name:	ConMed Linvatec
510(k) #:	K053561

Device Name:	ConMed Linvatec BioAnchor
Company Name:	ConMed Linvatec
510(k) #:	K042778

E. Device Description

The proposed device is a bioabsorbable push-in (press fit) suture anchor that is preloaded on a disposable inserter device with one or two non-absorbable, braided, polyethylene sutures. The proposed device is manufactured from 100% Poly L-lactic Acid with colorant D&C violet #2. The polymer is inert and non-collagenous through the absorption process. The device dimensions are 2.9mm diameter and 10.75mm in length.

F. Intended Use/ Indications

The anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules, to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

G. Substantial Equivalence

The proposed device is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices K053561 and K042778.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

ConMed Linvatec
% Ms. Lorna K. Linville
Regulatory Affairs Manager
11311 Concept Boulevard
Largo, Florida 33773-4908

OCT 1 7 2009

Re: K092898
Trade/Device Name: ConMed Linvatec Presto™, Preloaded with one or two #2 Hi-Fi Sutures
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI
Dated: September 18, 2009
Received: September 21, 2009

Dear Ms. Linville:

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 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K092898

Device Name: *ConMed Linvatec Presto™, Preloaded with one or two #2 Hi-Fi Sutures*

Indications for Use:

The anchors are intended to reattach soft tissue to bone in orthopedic surgical procedures. The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules, to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

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)

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

510(k) Number K092898