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APR 6 2006

March 1, 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMedLinvatec is hereby submitting the Special 510(k) Summary of Safety and Effectiveness for the Hi-Fi UltraFix Knotless Minimite Suture Anchor.

A. Submitter

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

B. Company Contact

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

C. Device Name

Trade Name:	Hi-Fi UltraFix Knotless Minimite Suture Anchor
Common Name:	Soft tissue fixation suture anchor
Classification Names:	888.3040 – Fastener, Fixation, Nondegradable, Soft Tissue
Proposed Class/Device:	Class II
Product Code:	MBI

D. Predicate/Legally Marketed Devices

K022827 – Ultrafix Knotless Minimite Suture Anchor

Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor
Special 510(k) # _____
March 1, 2006

E. Device Description

The Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor is a sterile, single-use, metal implant that is preloaded with high strength size 2 non-absorbable braided polyethylene suture.

The implanted anchor is manufactured from 316LS Stainless Steel, per ASTM/F-138, ISO 832-1 and is preloaded with a non-absorbable, braided, ultra-high molecular weight, polyethylene suture.

Intended Use

The Conmed Linvatec Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor is intended for reattaching soft tissue to glenoid bone in the shoulder. The following are the indications for use: Bankart lesions, SLAP lesions, capsular shifts, capsulolabral reconstructions.

F. Substantial Equivalence

Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor is substantially equivalent in indication for use, scientific technology and design to the UltraFix® Knotless Minimite® Suture Anchor. The UltraFix® Knotless Minimite® Suture Anchor was cleared by FDA under 510(k) K022827. The changes made to the predicate device have been tested to assure that the proposed modifications do not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

ComMed Linvatec
c/o Ms. Elizabeth Paul
Manager, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K060714
Trade/Device Name: Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: March 1, 2006
Received: March 17, 2006

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K060714

Device Name: Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor

Indications for Use:

The Conmed Linvatec Hi-Fi™ UltraFix® Knotless Minimite® Suture Anchor is intended for reattaching soft tissue to glenoid bone in the shoulder. The following are the indications for use: Bankart lesions, SLAP lesions, capsular shifts, capsulolabral reconstructions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use No
(Per 21 CFR 801.109)

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

510(k) Number K060714