FEB 2 3 2006

December 16, 2005

510(k) Submission

Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting a 510(k) Summary of Safety and Effectiveness for the Bio-Mini Revo Suture Anchor.

510(k) # K053561

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908

B. Company Contact

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

C. Device Name

Trade Name: Bio-Mini Revo Suture Anchor

Common Name: Bioabsorbable suture anchor

Classification Names: Biodegradable soft tissue fixation fastener

Proposed Class: Class II

Product Code: HWC/MAI

D. Predicate/Legally Marketed Devices

K042966 – Duet and Impact Suture Anchor (Linvatec Biomaterials)
K030388 – Impact Suture Anchor (Linvatec Biomaterials)
K020056 – Duet Suture Anchor (Linvatec Biomaterials)
K050497 – BioScrew XtraLok (ConMed Linvatec)
K020377 – BioStinger –V Bioabsorbable Meniscal Repair Device (ConMed Linvatec)
K991715 – BioStinger –V Bioabsorbable Meniscal Repair Device (ConMed Linvatec)

E. Device Description

The Linvatec Bio-Mini-Revo™ suture anchor is a bioabsorbale screw-in suture anchor that is preloaded on a disposable inserter device with one non-absorbable, braided, ultra-high molecular weight polyethylene suture. The Bio-Mini-Revo™ suture anchor is manufactured from Self-Reinforced (96/4D) PLA Copolymer. The Copolymer is inert, non-collagenous and non-pyrogenic through the absorption process. The device will be available in two versions; with or without colorant D&C violet #2.

F. Intended Use

The Bio-Mini Revo Suture Anchor ™ is intended for use in arthroscopic or open surgical procedures to reattach soft tissues to the bone.

G. Substantial Equivalence

The predicate devices are the previously cleared Linvatec Biomaterials Duet Suture Anchor (K020056, K042966) and Impact Suture Anchor (K030388, K042966), and ConMed Linvatec BioScrew XtraLok (K050497), Preloaded BioStinger Hornet (K020377), and BioStinger –V Bioabsorbable Meniscal Repair Device (K991715). These devices have substantially equivalent intended use, principles of operation and similar technological characteristics.

The difference when compared to Linvatec Biomaterials Duet Suture Anchor (K020056, K042966) and Impact Suture Anchor (K030388, K042966) is optional colored version. Production, the billet and machining of bioabsorbable implants are conducted in the same facility of Linvatec Biomaterials for all three anchors, Duet Suture Anchor (K020056, K042966), Impact Suture Anchor (K030388, K042966) and Bio-Mini-Revo. Polymer material is identical for all three implants, poly-96L/4D-lactide copolymer.

The technological difference between the proposed device and the BioScrew Xtralok (K050497), Preloaded BioStinger Hornet (K020377), and the BioStinger –V Bioabsorbable Meniscal Repair Device (K991715) is the material. The proposed Bio-Mini Revo Suture Anchor is manufactured from poly-96L/4D-lactide copolymer, where as the predicate devices listed above are manufactured from poly-L-lactide homopolymer. However, these devices are similar in that the D&C Violet #2 colorant is identical in the proposed device and these predicate devices.

The minor technological differences between Bio-Mini-Revo™ suture anchor and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2006

Ms. Elizabeth Paul
Manager, Regulatory Affairs
ConMed Linvatec
11311 Concept Blvd.
Largo, Florida 33773-4908

Re: K053561
Trade/Device Name: Bio-Mini-Revo™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MAI
Dated: December 16, 2005
Received: December 22, 2005

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 (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Acting 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): K05-3561

Device Name: Bio-Mini Revo Suture Anchor

Indications for Use:

The Bio-Mini Revo Suture Anchor is 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 OR Over-the-Counter Use No
(Part 21 CFR 801 subpart D) (Part 21 CFR 807 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 General, Restorative, and Neurological Devices

510(k) Number