K042966 page 1/2

NOV 19 2004

# 510(k) Summary
# Linvatec Biomaterials
# Modification of
# Duet™ and Impact™ Suture Anchor
# (K020056, K030388)

**Submitter's Name, Address, Telephone Number, and Contact Person**


Linvatec Biomaterials Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5600
Facsimile: 358-3-316 5629


**Date prepared:** August 11th, 2004

**Name of the device:**

| | | |
|---|---|---|
| A. | Trade or Proprietary Name: | Duet™ Suture Anchor and Impact™ Suture Anchor |
| B. | Common Name: | Bioabsorbable suture anchor |
| C. | Classification Name: | Biodegradable soft tissue fixation fastener (87MAI) |
| D. | Device Product Code: | MAI |
| E. | Regulatory Classification: | Class II |

**Predicate Devices:**

The predicate devices are the previously cleared Linvatec Biomaterials (the previous Bionx Implants) Duet™ Suture Anchor (K020056) and Impact™ Suture Anchor (K030388).

Duet™ Suture Anchor and Impact™ Suture Anchors are bioabsorbale suture anchors that are preloaded on a disposable inserter device with two non-absorbable sutures. Originally they were preloaded with non-absorbable, braided, polyester #2 sutures, one of them is green and another one is white

Purpose of this special 510(k) premarket notification is amendment of new preloaded suture material into Duet™ and Impact™ suture anchor product lines. The new suture, Herculine is non-absorbable, braided, ultra-high molecular weight polyethylene #2 suture. In coloured version 2 filaments are replaced by blue polypropylene monofilaments Herculine suture meets USP requirements for knot tensile strength and needle attachment strength.

The amendment of optional suture material has no effect on intended use, principles of operation, production methods, raw material or sterilization of Duet™ Suture Anchor (K020056) and Impact™ Suture Anchor (K030388).

**Substantial Equivalence:**

The new models have the following similarities to the cleared models of Duet™ Suture Anchor (K020056) and Impact™ Suture Anchor (K030388):

- has the same indicated use
- uses the same operating principle
- incorporates the same basic designs of implants
- is manufactured by machining
- is packaged and sterilized using the same materials and processes
- has the same shelf life

In summary, the amendment of new suture material described in this notification is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Linvatec Biomaterials Ltd.
P.O. Box 3
Hermiankatu 6-8 L
FIN 33721
Tampere, Finland

Re: K042966
Trade/Device Name: Duet™ and Impact™ Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: MAI, JDR
Dated: August 11, 2004
Received: October 28, 2004

Dear Ms. Annala:

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.

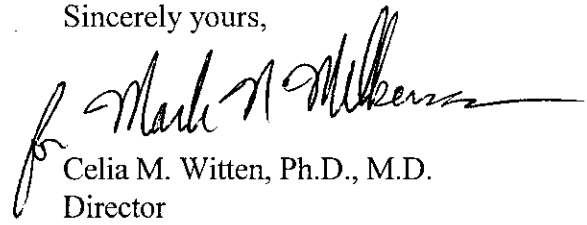
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Celia M. Witten, Ph.D., M.D.
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):** K042966

**Device Name:** **Duet™ and Impact™ Suture Anchor**

**Indications for Use:**

Duet™ and Impact™ Suture Anchors are intended for use to reattach soft tissue to bone in orthopaedic 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.

The Duet™ and Impact™ Suture Anchors are contraindicated in 1) Surgical procedures other than those listed, 2) Conditions that may compromise Anchor fixation (osteopenic, comminuted bone, pathologic conditions in the soft tissues to be attached, etc., 3) Conditions that may retard healing (poor blood supply, past or potential infection, etc), 4) Active infection, 5) Conditions that may limit the patients ability or willingness to restrict activities or follow directions during the healing period, 6) Foreign body sensitivity to materials, 7) Patients with suspected or known allergy with implant or suture materials.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-The-Counter Use No

(Per 21 CFR 801.109)

Mark N Milhern

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

**510(k) Number** K042966