

JUN 10 2004

**510(k) Summary  
Linvatec Biomaterials  
SmartPin**

**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  
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**Date prepared:** March 9, 2004

**Name of the device:**

- A. Trade or Proprietary Name: SmartPin
- B. Common Name: Bioabsorbable bone fixation pin
- C. Classification Name: Bone Fixation Pin
- D. Device Product Code: class II, HTY

**Predicate Device:**

1. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartPin® (the previous PLLA Pin) (K010983),
2. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartPin® PDX (the previous PLGA Pin) (K003659),
3. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) Biofix SR-PGA Pin (K890902),
4. Linvatec Biomaterials Ltd (the previous Bionx Implants, Inc.) SmartNail® (K993074, K031981)

**Intended Use:**

SmartPin® is indicated for fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments in the presence of appropriate immobilization.

**Device Description:**

The device description of SmartPin® is as follows:

- Composed of poly-96L/4D-lactide copolymer
- Tapered, smooth pins
- Lengths 10 - 70mm
- Diameters 1.1, 1.5, 2.0, 3.2 and 4.5 mm

The dimensions and shape are completely identical with Linvatec Biomaterials SmartPin® (the previous PLLA Pin) (K010983), SmartPin® PDX (the previous PLGA Pin) (K003659) and Biofix SR-PGA Pin (K890902).

**Substantial Equivalence:**

SmartPin® made of poly-96L/4D-lactide copolymer owns the following similarities to cleared devices SmartPin® (the previous PLLA Pin) (K010983), SmartPin® PDX (the previous PLGA Pin) (K003659) and Biofix SR-PGA Pin (K890902):

- has the same or similar indicated use
- use the same operating principle
- incorporate the same basic design
- is manufactured by same machinery
- is packaged and sterilized using the same materials and processes

In summary, SmartPin® described in this notification is, in our opinion, substantially equivalent to the predicate device.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K041288  
Trade/Device Name: SmartPin®  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HTY  
Dated: March 15, 2004  
Received: May 13, 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.

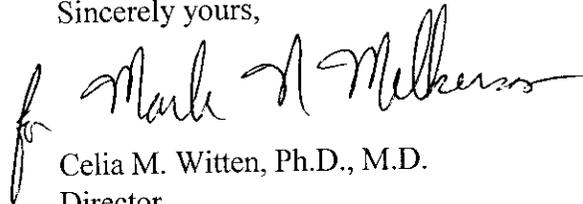
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Ms. Tuija Annala

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K041288

Device Name: SmartPin®

Indications for Use:

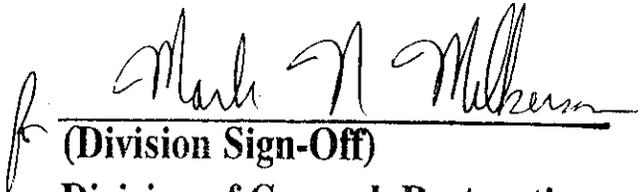
SmartPin® is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

SmartPin® is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) treatment of physal fractures in children, because the effect of SmartPin® upon the healing of growth plate has not been tested clinically.

(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)

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

510(k) Number K041288