K042295
1 of 2

SEP 1 6 2004

510(k) Summary
Linvatec Biomaterials
SmartScrew II

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

Linvatec Biomaterials Ltd.
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Date prepared: May 26, 2004

Name of the device:

A.	Trade or Proprietary Name:	SmartScrew II
B.	Common Name:	Bioabsorbable, Threaded, Fixation Rod
C.	Classification Name:	Biodegradable fixation fastener, bone
D.	Device Product Code:	HWC and MAI

Predicate Devices:

Linvatec Biomaterials (the previous Bionx Implants Inc). SmartScrew™ (K012001)

The predicate device is the previously cleared Linvatec Biomaterials (the previous Bionx Implants) Ø 2.0mm fully threaded, solid NuGenFX Screw (K012001). Purpose of this special 510(k) premarket notification is introduction of the new revised head design for Ø 2.0mm fully threaded, solid screw model and introduction of new trade name, SmartScrew® II.

Originally the screw head design of Ø 2.0mm fully threaded, solid NuGenFX Screw (K012001) was designed as a cloverleaf head. Further development of head design for smaller outer diameter and easier insertion of Ø 2.0mm screw model continued and finally new head design with outer attachment of screw driver was finalized. The main purposes were smaller size of screw head and improvement of installation properties without scarifying torsion properties of the screw model.

The revision of head design has no effect on intended use, principles of operation, production methods, raw material or sterilization.

The Ø 2.0mm fully threaded, solid SmartScrew® II has the following similarities to the cleared model Ø 2.0mm fully threaded, solid NuGenFX Screw (K012001):

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

In summary, the Ø 2.0mm fully threaded, solid SmartScrew® II 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

SEP 16 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: K042295
Trade/Device Name: SmartScrew® II
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: May 18, 2004
Received: August 24, 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,

Miriam C. Provost

for 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): K042295

Device Name: **SmartScrew® II**

Indications For Use:

SmartScrew® II is generally intended for maintenance of alignment and fixation of fractures, osteotomies, arthrodeses or condylar grafts within the condylar aspects of the upper extremity, ankle and foot, in the presence of appropriate brace and/or immobilization. Specifically, it is intended for phalangeal fusion and fracture, metacarpal fusion and fracture, carpal fusion and fracture, wrist arthrodesis, Distal radius fractures, olecranon fractures, radial head fractures, humeral condylar fractures, cancellous fractures and osteotomies of the malleolus, ankle fractures, metatarsal osteotomies and correction of hallux valgus.

SmartScrew® II is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except those in the hand and foot) and proximal femoral fractures. 2) Situations where internal fixation is otherwise contraindicated, e.g.. active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism). 3) Highly comminuted fractures, which would not be appropriate for fixation with metallic screws. 4) Patients with suspected or known allergy to the implant material.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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)

Miriam C. Provost

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

510(k) Number K042295