

510(K) SUMMARY

Ellipse PRECICE Trauma Nail System 510(k) Summary – K TBD December 2011

1. **Company:** Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Contact: John McIntyre
Vice President, RA/QA/CA
2. **Proprietary Trade Name:** Ellipse PRECICE Trauma Nail System
3. **Classification Name:** Rod, Fixation, Intramedullary and Accessories

(21 CFR 888.3020)
4. **Product Code:** HSB
5. **Product Description:**

The Ellipse PRECICE Trauma Nail System is composed of a modular implantable intramedullary rod (“Distracting Rod”), locking screws, an external remote controller (ERC), and surgical implantation tools and accessories. The modular implantable rod is available in different configurations, lengths, and diameters to accommodate a variety of patient anatomies. Likewise, the locking screws are available in two different diameters and a variety of lengths from 20 mm to 75 mm in 5 mm increments. The distracting rod is a modular system that includes the PRECICE Actuator component and various configurations of PRECICE Extension Rods. The PRECICE Actuator includes an enclosed rare earth magnet, telescoping lead screw/nut assembly and gearing. The PRECICE Actuator is supplied sterile by gamma sterilization while the PRECICE Extension Rods, locking screws, and reusable accessories are supplied non-sterile and must be sterilized prior to use.

The External Remote Controller (ERC) is a non-invasive adjustment component of the system. The ERC is electrically powered and is used for non-invasive lengthening of the implanted rod.

6. Indications

The Ellipse PRECICE Trauma Nail System is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

7. Substantial equivalence

Documentation demonstrates substantial equivalence to the following devices:

- Ellipse PRECICE Intramedullary Limb Lengthening System (K101997)
- Synthes Distraction Osteogenesis Ring System (K092190)
- Smith and Nephew Trigen Meta-Nail – Femoral and Tibial (K061019)

The purpose of this premarket notification is to provide labeling for this system for use in fracture fixation of long bones. Specifically, the following indication is included in the instructions for use:

The Ellipse PRECICE Trauma Nail System is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

Substantial equivalence is based on similar indications for use to both the Smith and Nephew Trigen Meta-Nail and Synthes Distraction Osteogenesis Ring System predicate devices and similar technological characteristics to the Ellipse PRECICE IMLL System, Smith and Nephew Trigen Meta-Nail and Synthes Distraction Osteogenesis Ring System predicates.

The Ellipse PRECICE Trauma Nail System is identical to the Ellipse PRECICE IMLL System, with the exception that the Ellipse PRECICE Trauma Nail is provided extended by approximately 10 mm to allow for compression fracture fixation techniques. Specifically, the Ellipse PRECICE Trauma Nail System and the Ellipse PRECICE IMLL System are both designed to be implanted into the medullary canal of the long bones. These devices are available in a variety of geometrical configurations and diameters and lengths to accommodate a variety of

Ellipse Technologies, Inc.
Ellipse PRECICE™ Trauma Nail System
Premarket Notification K113695
Response to telephone hold dated March 2, 2012

March 2012
Product Code: HSB

patient anatomies. Both devices are designed as a telescoping rod that can be adjusted in length non-invasively with the use of the ERC.

Review of the product designs and of the labeling demonstrate the equivalence of the Ellipse PRECICE Trauma Nail System to the predicate devices.

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

MAR 28 2012

Ellipse Technologies, Inc.
% Mr. John McIntyre
Vice President, RA/QA/CA
13900 Alton Parkway, Suite 123
Irvine, CA 92618

Re: K113695

Trade/Device Name: Ellipse PRECISE Trauma Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 23, 2012
Received: March 26, 2012

Dear Mr. McIntyre:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

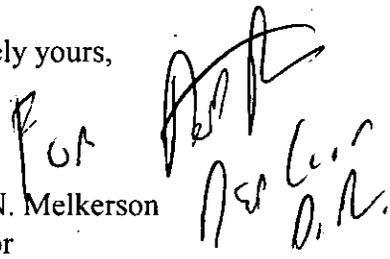
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


FOR
Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K113695 (pg 1/1)

510(k) Number: K113695

Device Name: Ellipse PRECICE Trauma Nail System

Indications for Use: The Ellipse PRECICE Trauma Nail System is indicated for closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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