DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2015

Ellipse Technologies Incorporated
John McIntyre
Vice President, Regulatory, Clinical, Quality Affairs
13900 Alton Parkway Suite 123
Irvine, California 92618

Re: K152370
Trade/Device Name: PRECICE Trauma Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 20, 2015
Received: August 21, 2015

Dear John 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 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Casey Hanley -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K152370

Device Name
PRECICE® Trauma Nail System

Indications for Use *(Describe)*
The Ellipse PRECICE Trauma Nail System is 152370indicated for open and closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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PRECICE Trauma Nail System
510(k) Summary
August 2015

1. **Company:** Ellipse Technologies, Incorporated
101 Enterprise Suite 100
Aliso Viejo, CA 92656

Contact: John McIntyre
VP, Regulatory, Clinical and Quality Affairs
Phone: (949) 837-3600 x203
Fax: (949) 837-3664

Date of Submission: August 19, 2015

2. **Proprietary Trade Name:** PRECICE Trauma Nail System

3. **Classification Name:** Intramedullary Fixation Rod (21 CFR 888.3020)

4. **Product Code:** HSB (Rod, Fixation, Intramedullary and Accessories)

5. **Product Description:** The PRECICE Trauma Nail System is composed of the PRECICE Trauma Nail (supplied sterile), locking screws, surgical instruments and an external remote controller (ERC or ERC 2P). The Nail is available in various diameters, lengths and screw-hole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters and lengths. The PRECICE Trauma Nail is supplied sterile by gamma radiation while the locking screws and instruments are supplied non-sterile and must be sterilized prior to use. The Nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. The Nail is supplied pre-distracted by 10 mm (femur and tibia models), 15 mm and 20 mm (humeral model) to allow for compression fracture reduction techniques.

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

7. **Substantial equivalence:** A detailed comparison to the predicate device demonstrates that the Ellipse PRECICE Trauma Nail System is substantially equivalent to the following 510(k) cleared device:

Trade Name:	PRECICE® Trauma Nail System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K142599

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Substantial equivalence is based on same indications for use, technological characteristics, principles of operation, designs, and on *in vitro* testing performed.

The modified PRECICE Trauma Nail System subject to this Special 510(k) and the predicate system have the same indications for use. Specifically, both systems are indicated for open and closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of long bones. This Special 510(k) is intended to include models specific for the humerus.

The modified Ellipse PRECICE Trauma Nail System has similar technological characteristics and the same principles of operation as that of the predicate. Both the current PRECICE Trauma Nails and the additional Humeral Trauma Nail models subject of this Special 510(k) are titanium intramedullary nails with a telescoping portion that can adjust the length of the limb using principles of distraction osteogenesis. Both devices are inserted into the intramedullary canal of the long bone and secured with PRECICE locking screws. Both devices are adjusted non-invasively by the Ellipse External Remote Controller (ERC). The differences between the two devices are dimensional to better fit the anatomy and fixation requirements of the humerus, and the pre-distracted length of the device.

Non-clinical testing of the PRECICE Trauma Nail System included design verification testing to ensure the device meets the retraction (compression) force and distraction force required for the humerus and cadaveric design validation testing to ensure the device can be inserted into the medullary canal and fixed to the humerus using the humeral specific instruments. The following specific performance tests were completed on the PRECICE Trauma Nail System in order to establish equivalence to the predicate device:

Test Description	Applicable Test Standard
Device Functionality and Verification	N/A
Design Validation	N/A

Non-clinical testing that was submitted for the predicate PRECICE Trauma Nail System which are applicable to the subject device include mechanical testing according to the methods outlined in the standard ASTM F1264-03, validation of the gamma radiation sterilization cycle in accordance with the VD_{max}^{25} methodology as given in ISO 11137-2 to verify that the gamma radiation sterilization process provides a sterility assurance level of 10^{-6}, shelf life testing for the packaging after accelerated aging, O-ring seal performance testing and biocompatibility in accordance with ISO 10993-1 for the intended use of the device.

There are no changes to the design of the ERC being made as a result of this submission, therefore all testing that was submitted for the ERC in the predicate PRECICE Trauma Nail System is applicable to the modified PRECICE Trauma Nail System.

Conclusions can be drawn from these tests that the modified PRECICE Trauma Nail System with the Humeral Trauma Nail line extension is substantially equivalent to the predicate device.