



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

Ellipse Technologies, Incorporated
Ms. Rebecca Shelburne
Regulatory Affairs Project Manager
13900 Alton Parkway, Suite 123
Irvine, California 92618

June 19, 2015

Re: K151131

Trade/Device Name: PRECICE[®] Intramedullary Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 1, 2015
Received: June 2, 2015

Dear Ms. Shelburne:

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" (21CFR 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)
K151131

Device Name
PRECICE® Intramedullary Limb Lengthening System

Indications for Use (Describe)
The Ellipse PRECICE System is indicated for limb lengthening of the tibia and femur.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRECICE® Intramedullary Limb Lengthening System
510(k) Summary – K 151131
April 2015

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

Contact: Rebecca Shelburne
Regulatory Affairs Project Manager
Phone: (949) 837-3600 x227
Fax: (949) 837-3664

Date Summary Prepared: April 27, 2015
2. **Proprietary Trade Name:** PRECICE Intramedullary Limb Lengthening System
3. **Common Name:** Intramedullary Nail
4. **Classification Name:** Intramedullary Fixation Rod (21 CFR 888.3020)
5. **Product Code:** HSB (Rod, Fixation, Intramedullary and Accessories)
6. **Product Description:** The Ellipse PRECICE System is composed of the PRECICE nail (supplied sterile), locking screws, surgical instruments and an external remote controller (ERC, ERC2P). The nail is available in tibia or femur models with 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 nail is supplied sterile by gamma radiation while the locking screws and PRECICE specific accessories 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.
7. **Indications for Use:** The Ellipse PRECICE System is indicated for limb lengthening of the tibia and femur.
8. **Substantial Equivalence:** Documentation that includes a performance assessment and detailed comparison to the predicate device demonstrates that the Ellipse PRECICE System is substantially equivalent to the following 510(k) cleared device:

Trade Name: Ellipse PRECICE System

Common Name: Intramedullary Nail

510(k) Clearance Number: K141023, K133289, K131677

Substantial equivalence is based on identical indications for use, technological characteristics and *in vitro* testing performed. The Risk Management file was updated to include the design modifications and no new risks were identified.

The additional length PRECICE nails that are subject of this premarket notification and the predicate device have the same indications for use. Specifically, both the predicate PRECICE

System and the PRECICE System that is subject of this Special 510(k) is indicated for limb lengthening of the tibia or femur. The additional length PRECICE nails are available in the same diameters and application. No changes are being made to the materials, technological characteristics or principles of operation as a result of this premarket notification. Both devices are inserted into the intramedullary canal of the femur or tibia and secured with locking screws. Both devices are adjusted non-invasively by the Ellipse external remote controller (ERC or ERC2P). The differences between the subject device and the predicate device are as follows:

- Shorter overall Nail lengths of 160-190 mm,
- Modified distal screw hole configuration,
- Modified locking rod interface on the proximal end of the housing tube,
- Chamfered screw holes on the targeting side of the proximal screw holes and a bulleted tip of the distraction rod, and
- Addition of new implantation instruments.

Data relied upon to determine substantial equivalence of the PRECICE System with the device modifications described in this submission to the cleared PRECICE System include the following:

Test Description	Applicable Test Standard
Static Torsion Testing	ASTM F1264
Tensile Strength Testing	N/A

There are no changes being made to the External Remote Controller (ERC or ERC 2P) or Locking Screws as a result of this submission.

Conclusions can be drawn from the tests that the modifications to the PRECICE System are substantially equivalent and meet the performance specifications.