



Food and Drug Administration
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April 4, 2016

Ellipse Technologies, Incorporated
Ms. Cora Sim
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K160325

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: February 4, 2016
Received: February 5, 2016

Dear Ms. Sim:

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,

Lori A. Wiggins -S

for

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)

K160325

Device Name

PRECICE Intramedullary Limb Lengthening System

Indications for Use (Describe)

The PRECICE Intramedullary Limb Lengthening 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Ellipse PRECICE® Intramedullary Limb Lengthening System
510(k) Summary – K160325
February 4, 2016

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

Contact: Cora Sim
 Regulatory Affairs Specialist
 Phone: (949) 837-3600 x221
 Fax: (949) 837-3664

Date of Submission: February 4, 2016
2. **Proprietary Trade Name:** PRECICE Intramedullary Limb Lengthening System
3. **Classification Name:** Intramedullary Fixation Rod (21 CFR 888.3020)
4. **Product Code:** HSB (Rod, Fixation, Intramedullary and Accessories)
5. **Product Description:** The Ellipse PRECICE Intramedullary Limb Lengthening System is composed of the PRECICE Nail (supplied sterile), locking screws, end cap, 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 surgical instruments are supplied non-sterile and must be sterilized prior to use.
6. **Indications:** The PRECICE Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femur.
7. **Substantial equivalence:** Documentation that includes a performance assessment, mechanical test results and detailed comparison to the predicate device demonstrates that the PRECICE Intramedullary Limb Lengthening System is substantially equivalent to the following 510(k) cleared device:
 - Ellipse PRECICE Intramedullary Limb Lengthening System (K151131)



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In addition, the PRECICE Intramedullary Limb Lengthening System designates the following 510(k) cleared reference device:

- Pega Medical, Incorporated Simple Locking IntraMedullary (SLIM) System (K143355)

Substantial equivalence is based on identical indications for use, technological characteristics, and on *in vitro* testing performed.

The PRECICE Intramedullary Limb Lengthening System and the predicate device have the same indications for use, similar technological characteristics, and the same principles of operation. Specifically, the subject PRECICE Intramedullary Limb Lengthening System and the predicate are both designed to lengthen the femur or tibia. This submission is for a line extension to the Ellipse PRECICE Intramedullary Nail to include additional shorter models with different locking screw hole patterns to the product line. An additional contraindication has also been added to the labeling for these models.

There are no changes to the design of the ERC or ERC2P being made as a result of this submission, therefore all testing that was performed on the predicate PRECICE Intramedullary Limb Lengthening System with regard to the ERC and ERC 2P are applicable.

Testing performed on the predicate Ellipse PRECICE Intramedullary Limb Lengthening System included sterilization validation, shelf life testing for the packaging and the device functionality, biocompatibility testing, and testing to ASTM F1264 for intramedullary rods. These results are also applicable to the subject PRECICE Intramedullary Limb Lengthening System.

The following additional tests have been performed on the subject PRECICE Intramedullary Limb Lengthening System in order to establish equivalence to the predicate device:

Test Description	Applicable Test Standard
Static Torque to Failure	ASTM F1264
Device functionality and verification	none

Conclusions can be drawn from the testing performed that the PRECICE Intramedullary Limb Lengthening System is substantially equivalent to the predicate device.