510(K) SUMMARY OR 510(K) STATEMENT

JAN 2 3 2014

Ellipse PRECICE® System
510(k) Summary – K131490
July 2013

Company:

Ellipse Technologies, Incorporated
13900 Alton Parkway, Suite 123
Irvine, CA 92618
Phone: (949) 837-3600
Fax: (949) 837-3664

FDA Establishment Registration No: 3006179046

Contact: John McIntyre
Vice President, RA/QA/CA

Proprietary Trade Name: Ellipse PRECICE® System

Common Name: Intramedullary Fixation Rod

Classification Name: Intramedullary Fixation Rod (21 CFR 888.3020)

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

Product Description:

The Ellipse PRECICE System is composed of an 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 second generation External Remote Controller (ERC 2P) which is the subject of this premarket notification, is a non-invasive adjustment component of the system. The

ERC 2P is an electrically powered handheld unit. The ERC 2P contains two large rare-earth magnets that are rotated using gears. After the rod has been implanted into the patient, the external device can be placed over the actuator portion of the implant and activated. When activated, the magnets within the ERC 2P rotate, which causes the magnet in the implantable device to rotate, lengthening or shortening the rod. Periodic lengthening (typically daily) of the rod is performed after the primary implantation surgery to lengthen the limb. The physician writes the patient prescription on an SD card which is placed in the ERC 2P. The distraction is confirmed in office using standard, routine x-ray of the limb. These office visits usually occur on a weekly basis.

Indications:

The Ellipse PRECICE System is indicated for limb lengthening of the tibia and femur.

Substantial Equivalence:

Documentation demonstrates substantial equivalence to the Ellipse System cleared under K101997 (cleared on July 12, 2011) and K113219 (cleared on October 19, 2012). The purpose of this premarket notification is to include a second generation External Remote Controller (ERC 2P) into the PRECICE® system. Data provided in this submission includes information relevant to the second generation ERC (ERC 2P). Substantial equivalence is based on similar indications for use, designs, *in vitro* testing, software validation, and Usability and labeling readability evaluations performed. The *in vitro* evaluations included specific tests performed on the ERC 2P to demonstrate the suitability of the device for its intended use, and electrical safety and electromagnetic compatibility tests. Usability evaluation of the ERC 2P in a representative population was performed to demonstrate its suitability for use by the proposed patient population in the home environment and in accordance with the indications.

The ERC 2P was designed to improve ergonomic handling and user interfaces, and has the same methods and principles of operation as the first generation ERC. The ERC 2P incorporates the controller and hand piece into one unit, to be more ergonomic and user friendly. The ERC 2P contains a camera and colored LCD-display screen to assist the

patient in proper alignment with the implant location. The second generation ERC for the Ellipse PRECICE System was developed and evaluated in accordance with recognized standards and with in-house developed test methodologies. This testing includes risk assessment of the device, testing to applicable IEC standards, and a usability study undertaken on 15 participants to evaluate the usability of the ERC 2P in an equivalent patient population. Risk analysis, draft labeling, and test results are included in this premarket notification. The results of testing demonstrate that the ERC 2P for the Ellipse PRECICE System that is the subject of this premarket notification is substantially equivalent to the predicate External Remote Controller device.

The following documentation and testing have been included in order to establish equivalence to the predicate device. Testing includes a usability evaluation for the Home Use of the ERC 2P by the patient, minimum rated voltage testing, shock and vibration testing, and ingress protection testing performed in accordance with IEC 60601-1-11;2010. The following tests have been performed in order to establish equivalence to the predicate device:

Test/Document Description	Applicable test standard
Risk Management Report	EN ISO 14971
Electrical Safety	IEC 60601-1 (3rd edition)
Electromagnetic Compatibility and Interference	IEC 60601-1-2
Minimum rated voltage testing	IEC 60601-1-11
Shock and Vibration Testing	
Ingress protection	
Labeling Readability	n/a
Usability evaluation	n/a

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2014

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

Re: K131490
Trade/Device Name: Ellipse PRECICE® System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 19, 2013
Received: December 20, 2013

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 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 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. 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,

Ronald P. Jean -S for

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)*
K131490

Device Name
Ellipse PRECICE® 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)*

Ronald P. FDJean -S

PSC Publishing Services (301) 443-6740 EF