February 23, 2018

Onkos Surgical, Inc.
Jan Triani
Regulatory Affairs
77 East Halsey Road
Parsippany, New Jersey 07054

Re: K180130
Trade/Device Name: ELEOS™ Bipolar Acetabular System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: January 16, 2018
Received: January 17, 2018

Dear Ms. Triani:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180130

Device Name
ELEOS™ Bipolar Acetabular System

Indications for Use *(Describe)*
The ELEOS™ Bipolar Acetabular System is indicated for the following conditions:
1) pathological fractures of the femoral neck
2) non-union of femoral neck fractures
3) aseptic necrosis of the femoral head and neck
4) primary pathology involving the femoral head or femur but with a non-deformed acetabulum.

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.

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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5. 510(k) Summary

I. SUBMITTER

Onkos Surgical, Inc.
77 East Halsey Road
Parsippany, NJ 07054

Phone: (201)543-9388

Contact Person: Jan Triani
Email: jtriani@onkossurgical.com

Date Prepared: February 15, 2018

II. DEVICE

Name of Device:	ELEOS™ Bipolar Acetabular System
Common Name:	Bipolar Hip System
Classification Name:	21 CFR 888.3390, Prosthesis, Hip, Hemi-, femoral Metal/Polymer, Cemented or uncemented – Class II
Regulatory Class:	II
Product Code:	KWY

III. PREDICATE DEVICE

GLADIATOR® Bipolar System, K062693

Reference Device: EVOLUTION Cementless Femur, K140735

IV. DEVICE DESCRIPTION

ELEOS™ Bipolar Acetabular System is a bipolar hip implant design that features a cross-linked polyethylene bearing surface with a lock detail enhanced for strength. Historical concerns with traditional bipolar designs have included loosening of the insert, disassociation of the head from the shell, and osteolysis resulting from polyethylene wear. This system is designed to address these concerns to give surgeons greater confidence when using a bipolar implant.

There is an UHMWPE support ring inside the shell that is permanently fixed. There is also an UHMWPE locking ring that assembles above the support ring and locks into place once the head is inserted into the shell. Bipolar heads are available in a variety of diameters with corresponding

internal diameters for 22, 28, 32 and 36mm femoral heads. Femoral heads with skirts are not compatible with the bipolar shells.

V. INDICATIONS FOR USE

The **ELEOS™ Bipolar Acetabular System** is indicated for the following conditions:

1)pathological fractures of the femoral neck

2) non-union of femoral neck fractures

3) aseptic necrosis of the femoral head and neck

4) primary pathology involving the femoral head or femur but with a non-deformed acetabulum.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICE

The predicate device and the subject device are the same. The same materials, technology and sterilization methods are used to manufacture the subject device. The predicate device manufacturer is the contract manufacturer of the subject device. There are no technological differences between the two systems.

VII. PERFORMANCE DATA

No performance data is provided. A copy of the full 510(k) for the predicate device (K062693) is provided because there are no technological differences between the subject and predicate devices. Non-pyrogenic status was determined using the LAL test with an identified acceptable testing limit. Testing to monitor pyrogens will be performed using periodic testing.

VIII. CONCLUSIONS

Since the subject device is the same as the predicate device, the ELEOS™ Bipolar Acetabular System has the same safety and effectiveness profile as the predicate device.