July 19, 2021

Intrauma S.p.A.
Via Genova, 19
Rivoli (TO) Italy 10098

Hollace Saas Rhodes
Vice President, Orthopedic Regulatory Affairs
MCRA LLC
1050 K Street NW
Washington DC 20001

Re: K201147
Trade/Device Name: Elos® Intramedullary Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 17, 2021
Received: June 17, 2021

Dear Hollace Saas Rhodes,

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K201147

Device Name

Elos® Intramedullary Nailing System

Indications for Use *(Describe)*

The short length Elos nails are intended for stabilizing various types of intertrochanteric fractures of the femur. The long length Elos nails are intended for fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, malunion, pathological fractures, and impending pathological fractures.

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.

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Intrauma S.p.A. 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Piero Costa
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Rivoli (TO) Italy 10098

Contact: Hollace Saas Rhodes
MCRA, LLC
1050 K Street, NW
Washington DC 20001
Ph: 202-552-5800

Date Prepared: July 16, 2021

Proposed Class: II

Proprietary Name: Elos® Intramedullary Nailing System

Common Name: Intramedullary Fixation Rod

Classification Name: Intramedullary Fixation Rod

Regulation Number: 21 CFR 888.3020

Product Codes: HSB

Predicate Device(s):

Manufacturer	Device Name	510(k) Number	Procode	Class
Stryker *(Howmedica Osteonics Corp)*	Gamma3™ Nail System	K032244	HSB	II
Stryker *(Howmedica Osteonics Corp)*	Gamma3™ Nail System	K034002	HSB	II

Indication for Use

The short length Elos nails are intended for stabilizing various types of intertrochanteric fractures of the femur. The long length Elos nails are intended for fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, malunion, pathological fractures, and impending pathological fractures.

Device Description

The Elos Intramedullary Nailing System consists of a titanium nail, cephalic screw, diaphyseal screw, optional closure cap, and a pre-assembled cannulated grub screw to lock cephalic screws. The short nails are available in lengths of 180mm and 240mm and 10mm and 11mm in diameter. The short nails also have CCD angles of 122° and 127°. The 180mm short nail is available in one configuration for both left and right femurs and the 240mm nail is available in both left and right configurations. The long length nails are 11mm in diameter, in lengths of 300mm, 340mm, 360mm, 380mm, 400mm, 420m, 440mm and 460 mm and are offered in left and right configurations. The long nails are also offered with CCD angles of 122° and 127°. The nails, screws, and closure cap undergo an anodic oxidation (Type II Anodization) treatment.

Performance Data

The Elos® Intramedullary Nailing System has been evaluated through non-clinical performance testing for mechanical fatigue. The testing demonstrated that the Elos® Intramedullary Nailing System components met performance requirements and are as safe and effective as their predicate devices.

Comparison of Technological Characteristics

The Elos® Intramedullary Nailing System has the same indications for use, materials, and similar design features as compared with the predicate systems. The bench testing demonstrates that the performance characteristics of the Elos® Intramedullary Nailing System are equivalent to those of other legally marketed intramedullary nail systems, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.

Substantial Equivalence

The subject device was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, function and performance.

Conclusion

The Elos Intramedullary Nailing System is substantially equivalent to the cited predicate device with respect to indications for use, design, function, and performance.