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MAR 2 5 2013

SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

Proprietary Name	SP2 Femoral Locking Nail, SP2 Tibial Locking Nail
Date Prepared	November 1, 2012
Submitter	Biomecanica Indústria E Comérico de Productos Ortopédicos Ltda Rua Luiz Pengo, 145-1° Distrito Industrial, CEP: 17.203-970 Jau, Sao Paulo, Brazil Telephone: 55 (14) 2104-7983
Official Contact	Tara Conrad and Lilian Llull TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077 FAX– (305) 377-0088
Common Name	Intramedullary Nail
Classification Name	Intramedullary Fixation Rod
Regulation Number & Product Codes	HSB-21 CFR §888.3020
Proposed Regulatory Class	Class II
Predicate Device Identification	T2 Femoral Nail K112059 Titan Tibial Nail K003018

Description of Proposed Device

The Biomecanica SP2 Femoral Locking Nail is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The Biomecanica SP2 Femoral Locking Nail may be inserted into the femoral canal using either a retrograde or antegrade surgical approach. The Biomecanica SP2 Femoral Locking Nail is currently available in diameters ranging from 9 to 12 mm and lengths ranging from 180 to 460 mm.

The Biomecanica SP2 Tibial Locking Nail is a temporary fixation intramedullary nail designed for fracture fixation and stabilizations of the tibia. The intramedullary nails are available in diameter ranging from 9 to 11mm and lengths ranging from 200 to

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440mm. Each of the nails is secured by a series of screws that pass through holds manufactured into the proximal and distal sections of each nail.

All components of the SP2 Femoral and Tibial Locking Nails are made of titanium alloy.

Intended Use

The SP2 Femoral Locking Nail, like the predicate Stryker T2 Femoral Nail, is a fracture fixation device comprised of femoral nails and the related locking screws, compression screws and end caps. The subject and predicate devices are intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

The SP2 Tibial Locking Nail, like the predicate Howmedica Osteonics Corporation Titan Tibial Nail K003018, is a fracture fixation device comprised of tibial nails and the related locking screws, compression screws and end caps. The subject and predicate devices are intended to provide strong and stable internal fracture fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

Indications for Use

The SP2 Femoral Locking Nail is indicated for long bone fracture fixation specifically femoral fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to the hip joint
- Nonunions and malunions

The SP2 Tibial Locking Nail is indicated for long bone fracture fixation specifically tibial fixation, which may include the following:

- Open or closed shaft fractures with a very proximal and very distal extent in which locking screw fixation can be obtained
- Pseudarthrosis
- Pathologic and impending pathologic fractures
- Multi-fragment fractures
- Segmental fractures
- Proximal or distal non-unions
- Proximal or distal mal-unions
- Corrective osteotomies
- Tumor resections
- Comminuted fractures with or without bone loss

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Substantial Equivalence

The information presented supports substantial equivalence of the Biomecanica SP2 Femoral Locking Nail and the T2 Femoral Nail manufactured by Stryker K112059. The information presented supports substantial equivalence of the Biomecanica SP2 Tibial Locking Nail and the Titan Tibial Nail by Howmedica Osteonics Corporation K003018. The proposed systems have the same intended uses, incorporates the same fundamental technology and is composed of the same material as the predicate devices. A tabular comparison between the SP2 Femoral and Tibial Locking Nails and cited predicates are included in this 510k.

Conclusion

This premarket notification is being submitted to request clearance for the SP2 Femoral and Tibial Locking Nails. The analysis on the SP2 Femoral and Tibial Locking Nails demonstrates substantial equivalence to the T2 Nail (K112059) and Titan Tibial Nail (K003018) predicates.

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

March 25, 2013

Biomecanica Indústria E Comérico de Productos Orthopédicos Ltda
% TechLink International Consulting
Ms. Tara Conrad
18851 NE 29th Avenue, Suite 720
Aventura, Florida 33180

Re: K123745
Trade/Device Name: SP2 Femoral Locking Nail SP2,Tibial Locking Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 7, 2013
Received: February 11, 2013

Dear Ms. Conrad:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Erin D. Keith

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

Enclosure

Indications for Use Statement

Device Name: SP2 Femoral Locking Nail and SP2 Tibial Locking Nail

510(k) Number: ~~(Pending)~~ K123745

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- Multi-fragment fractures
- Segmental fractures
- Proximal or distal non-unions

- Corrective osteotomies
- Tumor resections
- Comminuted fractures with or without bone loss

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR
Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices