March 3, 2023

Innosys Co., Ltd.
Yu-Jin Kang
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
Korea, South

Re: K221084
Trade/Device Name: Dyna Locking Trochanteric Nail™
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HTY
Dated: February 28, 2023
Received: March 1, 2023

Dear Yu-Jin Kang :

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.03.03 08:33:12 -05'00'

For Jiping Chen, M.D., Ph.D., M.P.H.
Division 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221084

Device Name
Dyna Locking Trochanteric Nail™

Indications for Use *(Describe)*
The Dyna Locking Trochanteric Nail™ is intended to be implanted into the intramedullary canal and head of femur for alignment, stabilization, fixation of fractures caused by trauma or disease including followings:
- Pertrochanteric fractures
- Intertrochanteric fractures
- Comminuted fractures
- Segmental fractures
- Fracture with bone loss
- Proximal and distal fractures
- Non-unions and malunions
- Subtrochanteric fractures(only for long nail: more than 320mm)

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.

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510(k) Summary

Manufacturer: Innosys Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,

Sponsor: Innosys Co., Ltd.
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, 11781, Korea,

Sponsor Contact: Yu-Jin Kang, RA Specialist
+82 31 860 6927
ujkang@inno-sys.net

Date Prepared: April 11, 2022

Device Name: Trade name: Dyna Locking Trochanteric Nail™

Classification Name: -Intramedullary Fixation Rod (HSB), per 21 CFR 888.3020
-Smooth or threaded metallic bone fixation fastener (HTY), per CFR888.3040

Common Name: Intramedullary Fixation System

Product Code: HSB, HTY

Predicate Devices:

- Primary - Dyna Locking Trochanteric Nail™ (K093707)
- Reference Device - PFNA-II Blade (K182783)

Purpose of submission:
The purpose of the current submission is
1) to add the new device, that does not have Wedge wings, which is different from the original device in the prior system(K093707).
2) to eliminate the separately registered Wedge wing and Neck screw that are already part of the Neck screw assembly.

Description of Device:
Dyna Locking Trochanteric Nail™ is consists of Trochanteric Nail for Femur, Neck Screw, Locking Screw for Distal Fixation, and Caps. Distal end part has hole and slot on the transverse direction for screw fixation. Proximal part is designed for neck screw and guide pin which is for insertion of anti-rotation guide wire. Above Neck screws have two types: built-in wedge wing type and without wedge wing type.
A built-in wedge wing Neck screw is used as an assembly, and a without wedge wing can be used alone. A user can select the type of Neck screw according to the condition of the patient. Distal part of trochanteric nail uses the cortical type screws.

All implants are single use only.

Indications For Use:
The Dyna Locking Trochanteric Nail™ is intended to be implanted into the intramedullary canal and head of femur for alignment, stabilization, fixation of fractures caused by trauma or disease including followings:

- Pertrochanteric fractures
- Intertrochanteric fractures
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- Segmental fractures
- Fracture with bone loss
- Proximal and distal fractures
- Non-unions and malunions
- Subtrochanteric fractures(only for long nail: more than 320mm)

Comparison Technological Characteristics
The predicate and proposed device have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same materials
- The equivalent mechanical performance

Performance Testing
Mechanical strength evaluations per ASTM F543 and geometrical comparisons to the predicate device demonstrate that the subject device's mechanical performance is substantially equivalent to the predicate device.

Conclusion
The data and information provided in this submission support the conclusion that the Dyna Locking Trochanteric Nail™ is substantially equivalent to predicate device with respect to indications for use and technological characteristics.