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

Cardinal Health
Ms. Kyungyoon Kang
Regulatory Affairs Manager
720 South Colorado Boulevard, Suite 550S
Denver, Colorado 80246

December 14, 2015

Re: K150769
Trade/Device Name: Cardinal Health Trochanteric IM Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 7, 2015
Received: November 12, 2015

Dear Ms. 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. 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K150769

Device Name: **Cardinal Health Trochanteric IM Nail System**

Indications for Use: The Cardinal Health Trochanteric IM Nail System is intended to provide temporary fixation of the femur for various types of open or closed fractures including malunions, nonunions (pseudoarthrosis), pathologic fractures, and impending pathologic fractures. Fracture types include pertrochanteric fractures, intertrochanteric fractures, basal neck fractures. Long Length Nails: Fracture types include pertrochanteric fractures, subtrochanteric fractures, intertrochanteric fractures, femoral shaft fractures, and basilar neck fractures.

Prescription Use X or Over-The-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

NAME OF FIRM: Cardinal Health
1500 Waukegan Road
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DATE PREPARED: March 17, 2015

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PROPOSED TRADE NAME: Cardinal Health Trochanteric IM Nail System

DEVICE CLASSIFICATION: Class II; 21 CFR 888.3020

CLASSIFICATION NAME: Intramedullary fixation rod

PRODUCT CODE: HSB

DEVICE DESCRIPTION: The System consists of titanium alloy intramedullary (IM) nails, locking screws and end caps. The rigid, cannulated IM nails are inserted into the medullary canal and available in a variety of styles and lengths with proximal and distal holes for locking screws.

INDICATIONS FOR USE: The Cardinal Health Trochanteric IM Nail System is intended to provide temporary fixation of the femur for various types of open or closed fractures including malunions, nonunions (pseudoarthrosis), pathologic fractures, and impending pathologic fractures. Fracture types include pertrochanteric fractures, intertrochanteric fractures, basal neck fractures. Long Length Nails: Fracture types include pertrochanteric fractures, subtrochanteric fractures, intertrochanteric fractures, femoral shaft fractures, and basilar neck fractures.

MATERIALS: Titanium alloy (ASTM F136)

PREDICATE DEVICES: Stryker Gamma 3 Nail System (K034002); Previously Cleared Emerge Medical IM Nail System & Screws (K141347) is used as a reference device in this submission.

TECHNOLOGIC CHARACTERISTICS: The Cardinal Health Trochanteric IM Nail System incorporates the same design elements as the predicate devices. The material composition is the same and the sizing comparable. The Cardinal Health (subject) and predicate both incorporate rigid, cannulated, reamed, IM nails with static and dynamic locking options. All incorporate proximal and distal screws for static and dynamic properties, as well as end caps and trochanteric set screws for fixation. For the Cardinal Health Trochanteric IM Nail System, as well as the predicate, targeting devices are used routinely for placement of the lag screw and freehand placement with image verification is used for distal screw placement. Differences between the Cardinal and predicate devices include different sizes and fewer options. These differences do not impact safety and effectiveness, as demonstrated by the performance testing.

PERFORMANCE DATA The following performance data were provided in support of the substantial equivalence determination.

Mechanical Testing

Testing was performed according to ASTM F1264-03 (Reapproved 2012) Standard Specification and Test Methods for Intramedullary Fixation Devices and ASTM F543-13e1 Standard Specification and Test Method for Medical Bone Screws

CONCLUSIONS The mechanical testing demonstrates that the Cardinal Health Trochanteric IM Nail System should perform as well as the predicate device in the specified use conditions.