Depuy Synthes
Rebecca Reiter
Senior Regulatory Affairs Program Lead
1301 Goshen Parkway
West Chester, Pennsylvania 19380

August 1, 2024

Re: K233696
Trade/Device Name: DePuy Synthes Retrograde Femoral Nail Advanced System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 3, 2024
Received: July 3, 2024

Dear Rebecca Reiter:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve

changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2024.08.01 10:29:27 -04'00'

Farzana Sharmin, PhD
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*
K233696

Device Name
DePuy Synthes Retrograde Femoral Nail Advanced System

Indications for Use *(Describe)*
The DePuy Synthes Retrograde Femoral Nail Advanced System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- Supracondylar fractures, including those with intra-articular extension
- Combination of ipsilateral condylar and diaphyseal fractures
- Ipsilateral femur/tibia fractures
- Femoral fractures in multiple trauma patients
- Periprosthetic fractures
- Fractures in the morbidly obese
- Fractures in osteoporotic bone
- Impending pathologic fractures
- Malunions and nonunions

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.

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510(k) #: K233696

510(k) Summary

Prepared on: 2024-07-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Depuy Synthes
Applicant Address	1301 Goshen Parkway West Chester PA 19380 United States
Applicant Contact Telephone	+1-610-719-1268
Applicant Contact	Mrs. Rebecca Reiter
Applicant Contact Email	rreiter@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DePuy Synthes Retrograde Femoral Nail Advanced System
Common Name	Intramedullary fixation rod
Classification Name	Rod, Fixation, Intramedullary And Accessories
Regulation Number	888.3020
Product Code(s)	HSB, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201346	DePuy Synthes Retrograde Femoral Nail Advanced System	HSB
K033618	Synthes Retrograde/Antegrade Femoral Nail	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The DePuy Synthes Retrograde Femoral Nail Advanced System was developed to address challenges associated with treating distal femur fractures with intramedullary nails. The modular system incorporates several components to allow for the treatment of a variety of fracture patterns including those in the presence of previously implanted devices such as the femoral components of a total knee arthroplasty (periprosthetic). The nailing implants are available in two distal bend configurations which enable standard and periprosthetic entry points for the insertion of the nailing implant in the femur. The nailing system implants are manufactured from titanium alloys, stainless steel and polyethylene and are provided in a range of dimensions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The DePuy Synthes Retrograde Femoral Nail Advanced System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- Supracondylar fractures, including those with intra-articular extension
- Combination of ipsilateral condylar and diaphyseal fractures
- Ipsilateral femur/tibia fractures
- Femoral fractures in multiple trauma patients
- Periprosthetic fractures
- Fractures in the morbidly obese
- Fractures in osteoporotic bone
- Impending pathologic fractures

- Malunions and nonunions

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject DePuy Synthes Retrograde Femoral Nail Advanced System has the same intended use, indications for use and principles of operation, and similar technological characteristics as compared to the predicate and reference devices. The only difference between the subject device and the predicate is the option to remove the polymer inlay prior to intraoperative placement. This added option does not present any new concerns of safety or effectiveness as compared to the predicate device cleared under K201346 and reference device cleared under K033618. Thus, the DePuy Synthes Retrograde Femoral Nailing Advanced System is substantially equivalent to the DePuy Synthes Retrograde Femoral Nail Advanced System, DePuy Synthes Locking Screws for Medullary Nails, 5.0mm (K201346).

Technological Comparison 21 CFR 807.92(a)(6)

The subject Retrograde Femoral Nailing Advanced (RFN-A) System has the same intended use, indications for use and principles of operation, and similar technological characteristics as compared to the predicate and reference devices. The only difference between the subject device and the predicate is the option to remove the polymer inlay prior to intraoperative placement. This added option does not present any new concerns of safety or effectiveness as compared to the predicate device cleared under K201346. Thus, the DePuy Synthes RFN-A System is substantially equivalent to the DePuy Synthes Retrograde Femoral Nail Advanced System, DePuy Synthes Locking Screws for Medullary Nails, 5.0mm (K201346).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was performed on the subject RFN-A with the inlay removed, in order to adequately assess substantial equivalence against the predicate RFN-A (as provided, with the inlay). A non-inferior change to resistance to screw cut through was observed when testing the subject RFN-A with the inlay removed, vs. the predicate RFN-A as provided, with the inlay.

Additionally, the RFN-A Nail without inlay + Locking Attachment Washer (LAW) construct demonstrated a higher superior peak cutout force when subjected to static loading in a foam model compared to the RFN-A Nail without inlay + locking screws construct.

Additionally, MR testing was performed to substantiate the MR Conditional claim for the RFN-A Nail.

The tests results meet established acceptance criteria to support the substantial equivalence determination of the subject device with the inlay removed vs. the predicate RFN-A with the inlay.