March 18, 2022

DePuy Synthes
Quinn Mccarthy
Senior Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K213563
Trade/Device Name: DePuy Synthes Radial Head Replacement System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow Joint Radial (Hemi-Elbow) Polymer Prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: January 28, 2022
Received: January 31, 2022

Dear Quinn Mccarthy:

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,

Lixin Liu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213563

Device Name
DePuy Synthes Radial Head Replacement System

Indications for Use *(Describe)*
•Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
- o joint destruction and/or subluxation visible on x-ray; and/or
- o resistance to conservative treatment.

• Primary replacement after fracture of the radial head.
• Symptomatic sequelae after radial head resection.
• Revision following failed radial head arthroplasty.

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) Summary

Sponsor	DePuy Synthes Quinn McCarthy 1301 Goshen Parkway West Chester, PA 19380 Phone: (732) 947 2251
Date Prepared	March 04, 2022
Proprietary Name	DePuy Synthes Radial Head Replacement System – MR Conditional
Classification Name	Elbow joint radial (hemi elbow) polymer prosthesis
Classification	Class II Regulation Number: 21 CFR §888.3170 Product Code: KWI
Predicate Device	Revolution Radial Head - K183618
Device Description	This document is regarding the DePuy Synthes Radial Head Replacement System-MR Conditional. The Radial Head Replacement System Implant is a one-piece, stemmed radial head replacement. The radial head is available in diameters of 19, 22 and 25mm. The radial stems range from 5.5 to 8.5mm in diameter and from 21 –24mm in length. The Radial Head is manufactured from wrought CoCrMo alloy. The system is provided with a set of accessory instruments designed for preparation of the implant site and insertion of the implants into bone. The devices in scope of the subject submission are being reviewed for MR Conditional labeling in addition to the previously cleared indications for use.
Indications for Use	• Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with: o joint destruction and/or subluxation visible on x-ray; and/or o resistance to conservative treatment. • Primary replacement after fracture of the radial head. • Symptomatic sequelae after radial head resection. • Revision following failed radial head arthroplasty.

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Contraindications	Absolute contraindications include: Infection, sepsis, osteomyelitis. Relative contraindications include: Uncooperative patient or patient with neurologic disorders who are incapable of following directions, osteoporosis, metabolic disorders which may impair bone formation, osteomalacia, distant foci of infections which may spread to the implant site, rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
Comparison to Predicate	The purpose of this submission is to add MR Conditional information to the device labeling for the DePuy Synthes Radial Head Replacement System – MR Conditional, K183618. The intended use and technological characteristics of the devices remains unchanged. The device name has been updated to reflect the current company name, DePuy Synthes, previously cleared as the Revolution Radial Head and now renamed to the DePuy Synthes Radial Head Replacement System – MR Conditional. The materials of the devices remain unchanged from K183618 (CoCrMo alloy conforming to ASTM F1537). The technical characteristics of the device remain unchanged from the predicate K183618: • One-piece • Head diameters of 19, 22 and 25mm • Head Heights of 9-15, 10-16, 11-17mm • Stem diameters 5.5 – 8.5mm • Stem lengths 21-24mm • Radial head thickness 9 – 17mm • Articular depth 1.6 – 2.6mm
Non-Clinical Performance Data	This submission includes non-clinical testing to support the conditional safety of the DePuy Synthes Radial Head Implants in the Radial Head Replacement System in the MR environment. The testing includes magnetically induced displacement force (ASTM F2052-15) and torque (ASTM F2213-17), radio frequency (RF) heating (ASTM F2182-11a), and image artifacts (ASTM F2119-07 (2013)). The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no different questions of safety or effectiveness.
Clinical Performance Data	Clinical testing was not necessary for the determination of substantial equivalence.

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Substantial Equivalence	The subject device has the same intended use compared to the predicate device. The technological characteristics of the device remain unchanged. It is concluded that the information provided herein supports substantial equivalence of the subject devices to the predicate device, K183618.