June 16, 2020

DePuy Orthopaedics, Inc.
Melissa Cook
Regulatory Affairs Specialist III
700 Orthopaedic Dr.
Warsaw, Indiana 46582

Re: K193540
Trade/Device Name: TRUMATCH Personalized Solutions
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG
Dated: May 15, 2020
Received: May 18, 2020

Dear Melissa Cook:

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,

for Ting Song, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K193540

Device Name

TRUMATCH Personalized Solutions

Indications for Use *(Describe)*

The TruMatch Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting. The anatomical landmarks necessary for the creation of the TruMatch Patient Specific Instruments must be present and identifiable on CT. The TruMatch Patient Specific Instruments are intended for use with Sigma Total Knee Implants and Attune Total Knee Implants and their cleared indications for use. The TruMatch Patient Specific Instruments are intended for single use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

(As required by 21 CFR 807.92)

Submitter Information	
Name	DePuy Orthopaedics, Inc.
Address	700 Orthopaedic Dr. Warsaw, IN 46582
Phone number	574-371-4906
Establishment Registration Number	1818910
Name of contact person	Melissa Cook
Date prepared	June 16, 2020
Name of device	
Trade or proprietary name	DePuy TRUMATCH Personalized Solutions
Common or usual name	Total knee prosthesis instrumentation
Classification name	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3560
Product Code(s)	JWH, OOG
Legally marketed device(s) to which equivalence is claimed	TRUMATCH Personalized Solutions, K110397 Reference device: TRUMATCH Personalized Solutions, bundled P830055/S217
Reason for 510(k) submission	Device modification - This submission seeks clearance for changes to the software that enable the TRUMATCH surgical plan and Guides to be designed for a patient specific alignment surgical technique.
Device description	The TRUMATCH Personalized Solutions System is comprised of patient-specific instruments and the software utilized to design the patient-specific surgical plans and instruments. The predicate TRUMATCH System creates a surgical plan based on a mechanical axis surgical technique. Changes to the Planning software component allow the surgeon to select a mechanical axis surgical technique or a patient-specific alignment surgical technique. Upon approval of the surgical plan, the TRUMATCH Guides are manufactured according to the plan.

Intended use of the device	Intended for patients with osteoarthritis who: • Meet the criteria for primary total knee replacement performed with a measured resection technique. • Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus/valgus, or flexion. • Have some previous implants, such as hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan.
Indications for use	The TRUMATCH Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting. The anatomical landmarks necessary for the creation of the TRUMATCH Patient Specific Instruments must be present and identifiable on CT. The TRUMATCH Patient Specific Instruments are intended for use with Sigma Total Knee Implants and Attune Total Knee Implants and their cleared indications for use. The TRUMATCH Patient Specific Instruments are intended for single use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristics	**Subject Device: TRUMATCH Personalized Solutions**	**Predicate Device: TRUMATCH Personalized Solutions (K110397)**
Intended Use	Intended for patients with osteoarthritis who: • Meet the criteria for primary total knee replacement performed with a measured resection technique. • Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus/valgus, or flexion. • Have some previous implants, such as hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan.	Same
Material	Accura and Stainless Steel	Same
Image Inputs	CT Images	Same
Software Packages	TRUMATCH 3.0 System software	TRUMATCH 2.5 System software
Size	Patient-specific	Same
Implant Compatibility	Used with the implantation of the ATTUNE and SIGMA Total Knee Implants	Same
Packaging, Sterilization and Shelf Life		
Sterile Method	Gamma	Same
Packaging	Polyurethane bag within a single blister tray, sealed with Tyvek lid, placed in unit carton	Same
Shelf Life	185 Days	120 days

The subject TRUMATCH Personalized Solutions is the same as the predicate TRUMATCH Personalized Solutions (K110397) in intended use, design, and materials. The subject and predicate devices are intended to be used as patient-specific surgical instrumentation in total knee arthroplasty. The subject device utilizes the same software system components as the reference device TRUMATCH Personalized Solutions (bundled P830055/S217). The subject device is modified to enable either a mechanical axis alignment or patient specific alignment surgical technique.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The following tests were performed to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Model creation process verification for Patient Specific Alignment Guides
- Cadaver lab with simulated surgery for assessment of guide fit, implant alignment and size, and bone resection accuracy analysis
- Software verification testing

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSION DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject device TRUMATCH Personalized Solutions System is substantially equivalent to the predicate TRUMATCH Personalized Solutions System.