DePuy Orthopaedics, Inc.
% Sierra Robinson
Regulatory Affairs Specialist II
Depuy Ireland UC
Loughbeg, Ringaskiddy, Co. Cork
IRELAND

August 22, 2023

Re: K231503
Trade/Device Name: CUPTIMIZE™ Advanced
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 25, 2023
Received: July 27, 2023

Dear Sierra Robinson:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: Office of Radiological Health
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.

Submission Number *(if known)*

K231503

Device Name

CUPTIMIZE™ Advanced

Indications for Use *(Describe)*

CUPTIMIZE™ Advanced is an image-processing software indicated to assist in the positioning of total hip replacement components, with a specific focus on the acetabular component.

It is intended to assist in the precise positioning of the acetabular component intra-operatively by measuring its position relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

The device allows for overlaying of digital annotations on radiological images and includes tools for performing measurements using the images and digital annotations. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

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.

K231503 510(k) Summary

Prepared on: 2023-05-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	DePuy Orthopaedics, Inc
Applicant Address	700 Orthopaedic Dr Warsaw IN 46582 United States
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Applicant Contact	Sierra Robinson
Applicant Contact Email	srobin24@its.jnj.com
Correspondent Name	Depuy Ireland UC
Correspondent Address	Loughbeg, Ringaskiddy Co. Cork Ireland
Correspondent Contact Telephone	8502519921
Correspondent Contact	Sierra Robinson
Correspondent Contact Email	srobin24@its.jnj.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CUPTIMIZE™ Advanced ( )
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203651	Cuptimize	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

CUPTIMIZE™ Advanced is a software as a medical device (SaMD) system that provides acetabular component orientation data for hip replacement surgery., The software guides the user through a workflow that involves positioning digital annotations on preoperative patient radiographic images.CUPTIMIZE™ Advanced utilizes digital annotations to describe the range of motion of the pelvis and provides an orientation of the acetabular component which reduces risk of edge loading and implant-implant impingement. The system also provides warnings for patients with high or low pelvic mobility and high or low pelvic incidence.

CUPTIMIZE™ Advanced will include a pre-operative module that determines spinopelvic tilt relationships and data to provide an implant orientation plan, as well as an intra-operative verification capability that will allow the current implant orientation to be assessed against the plan.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

CUPTIMIZE™ Advanced is an image-processing software indicated to assist in the positioning of total hip replacement components, with a specific focus on the acetabular component.

It is intended to assist in the precise positioning of the acetabular component intra-operatively by measuring its position relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

The device allows for overlaying of digital annotations on radiological images and includes tools for performing measurements using the images and digital annotations. Clinical judgment and experience are required to properly use the software. The software is not for primary image interpretation. The software is not for use on mobile phones.

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

The indications for use are the same as the predicate device, Cuptimize (K203651).

Technological Comparison 21 CFR 807.92(a)(6)

The subject CUPTIMIZE Advanced is the same as the predicate CUPTIMIZE in intended use, classification, and principles of operation.

The subject CUPTIMIZE Advanced and the predicate CUPTIMIZE both provide guidance on acetabular cup orientation based on a patient's pelvic mobility. The subject device provides a component orientation which avoids edge loading and implant-implant impingement.

The subject CUPTIMIZE Advanced and the predicate CUPTIMIZE both have an interoperative workflow that allows the intraoperative implant orientation to be assessed against the preoperative plan.

The subject CUPTIMIZE Advanced and the predicate CUPTIMIZE both are intended to be integrated as a module within VELYS Hip Navigation.

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

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

- Model verification tests
- System verification tests
- System validation tests
- Usability evaluation

Clinical testing was not required to demonstrate substantial equivalence.

The subject device, Cuptimize Advanced is substantially equivalent to the predicate device.