Cuptimize, Inc.
% Ms. Michelle McDonough
Senior Director, Regulatory and Clinical Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
WASHINGTON DC 20001

February 26, 2021

Re: K203651
Trade/Device Name: Cuptimize
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 23, 2020
Received: December 23, 2020

Dear Ms. McDonough:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203651

Device Name
Cuptimize

Indications for Use *(Describe)*
Cuptimize 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.

510(k) Summary

K203651

Manufacturer: Cuptimize, Inc.
2840 West Bay Drive, Unit #163
Belleair Bluffs, FL 33770

Contact: Michelle McDonough, MS
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
202.552.5800 (phone)
202.552.5798 (fax)

Date Prepared: February 18, 2021

Device Trade Name: Cuptimize

Common Name: Picture archiving and communications system (PACS)

Classification: 21 CFR 892.2050

Class: II

Product Code: LLZ; HAW

Indications for Use:
Cuptimize 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.

Device Description:
Cuptimize is a software as a medical device (SaMD) system that provides acetabular component position data for hip replacement surgery. The software guides the user through a workflow that involves positioning a series of digital annotations on preoperative and intraoperative radiographic

images. This enables the system to calculate inclination and anteversion data that describes the acetabular component position.

Predicate Devices:
Cuptimize is substantially equivalent to JointPoint (K160284).

Verification and Validation Testing Summary:
Verification activities included system and unit testing via automated regression testing and manual test procedure analyses. Validation testing was performed to analyze acetabular component position on a cadaver by comparing output data from the Cuptimize system to the output of a predicate device, JointPoint.

Substantial Equivalence:
Cuptimize and JointPoint are both image-processing software indicated to assist in the positioning of total hip replacement components. The Cuptimize software is focused on a sub-set of the capabilities of the JointPoint system, specifically the acetabular component. Both devices assist in positioning of the acetabular component by measuring the position relative to the bone structures of interest provided that the points of interest can be identified from radiology images.

Testing performed on this device demonstrates that Cuptimize is substantially equivalent to the predicate device. Performance testing of the Cuptimize system included reproducible verification and validation scripts using known measurements to establish data against a measured control. Additionally, anteversion and inclination data was compared against analysis from the JointPoint predicate device (510k clearance "K160284"). Finally, a cadaveric laboratory was performed to gather data to validate the system's intended use and to perform sensitivity testing.

Predicate Comparison Table

	Subject Device	**Predicate Device**
Device Name	Cuptimize	JointPoint
Company	Cuptimize, Inc.	JointPoint, Inc.
K Number	Subject Device	K160284
Classification	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ; HAW	LLZ; HAW
Indications for Use Statement	Cuptimize 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	JointPoint is an image-processing software indicated to assist in the positioning of total hip replacement components. It is intended to assist in precisely positioning total hip replacement components intra-operatively by measuring their positions relative to the bone structures of interest provided that the points of interest can be identified from radiology images. JointPoint is also indicated for assisting healthcare professionals in preoperative planning and postoperative analysis of

	Subject Device	Predicate Device
Device Name	Cuptimize	JointPoint
	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.	orthopedic surgery in Total Hip Replacement, Total Knee Replacement, and Intertrochanteric Fracture Reduction. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. 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.
Components	Identical	Identical
Computer	Identical	Identical
Operating Systems	Identical	Identical
Anatomical Locations	Hip	Hip; Knee
Input Data	Identical	Identical
Output Data	Measurements and calculations for cup position analysis.	Measurements and calculations for cup position analysis, leg length and offset analysis, contralateral leg length analysis and intertrochanteric fracture reduction analysis.
Software Features	Preoperative and intraoperative cup position analysis.	Preoperative leg length and offset analysis, interoperative cup position analysis, leg length and offset analysis, contralateral leg length analysis and intertrochanteric fracture reduction analysis.
V&V Testing	All Unit and System Tests Passed	All Unit and System Tests Passed
Cadaver Data – Cup Check	Inclination and Anteversion substantially equivalent to JointPoint	

Conclusion:

Cuptimize is shown to be substantially equivalent to previously cleared devices with respect to its intended use, indications for use, technological characteristics, and performance characteristics.