Blue Belt Technologies, Inc.
Amy Winegarden
Senior Regulatory Affairs Specalist
2905 Northwest Boulevard, Suite 40
Plymouth, MN 55441

Re: K212040
Trade/Device Name: Ri.hip Modeler
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: [NOTE: Use date of most recent supplement]
Received: February 10, 2022

Dear Amy Winegarden:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212040

Device Name
RI.HIP MODELER

Indications for Use *(Describe)*
RI.HIP MODELER is intended for preoperative planning for primary total hip arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty.

RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.

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

510(k) Owner	Blue Belt Technologies, Inc. 2905 Northwest Blvd Ste. 40 Plymouth, MN 55441 USA Tel: (763) 452-4950 Fax: (763) 452-4675
Contact Person	Michael Gosha Regulatory Affairs Specialist II Email: Michael.Gosha@Smith-Nephew.com Phone: 216-816-6728
Date of Submission	June 29, 2021
Classification Reference	21 CFR 892.2050
Product Code	LLZ
Common/Usual Name	Picture archiving and communications system
Trade/Proprietary Name	RI.HIP MODELER™
Predicate Device(s)	OneFit Medical - hipEOS (K173390)
Reason for Submission	New Device

Indications for Use

RI.HIP MODELER is intended for preoperative planning for primary total hip arthroplasty. RI.HIP is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty.
RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.

Device Description

RI.HIP MODELER is a non-invasive standalone Total Hip Arthroplasty (THA) planning software application intended to provide preoperative planning for hip implant acetabular cup rotational selection and placement. RI.HIP MODELER allows surgeons to visualize and perform analysis of digital images for assessment of spinopelvic mobility of the patient. The app is used to characterize patient conditions, manage patient performance expectations, and help surgeons determine acetabular cup placement based on spinopelvic mobility.

The software provides a baseline cup orientation recommendation intended to reduce incidences of implant impingement based on patient condition and implant specifications. The surgeon is reminded to verify and adjust to the parameters based on their clinical judgment.

Discussion of Similarities and Differences

RI.HIP MODELER is substantially equivalent to the predicate device hipEOS (K173390). The intended use and the established technologies used for preoperative planning of Total Hip Arthroplasty and placement of THA implants, is the same as the predicate device. The table below compares the RI.HIP MODELER, the subject device, to hipEOS, the predicate device. A discussion of the differences follows.

Parameter	Subject Device RI.HIP MODELER	Predicate Device hipEOS (K173390)
Intended Use [Substantially Equivalent][1]	RI.HIP MODELER is intended for preoperative planning for primary total hip arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty. RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.	hipEOS software is indicated to be used for assisting healthcare professionals in preoperative planning of total hip arthroplasty (THA). The software allows for overlaying of 3D/2D hip implant models on radiological images or reconstruction of bone and includes tools for performing measurements on the image or model of bones and for selecting and positioning the implant models. Clinical judgments and experience are required to properly use the software.
Indications for Use [Substantially Equivalent][1]	RI.HIP MODELER is intended for preoperative planning for primary total hip arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary total hip arthroplasty. RI.HIP MODELER is indicated for individuals undergoing primary hip surgery.	hipEOS software is indicated to be used for assisting healthcare professionals in preoperative planning of Total Hip Arthroplasty (THA). The software allows for overlaying of 3D/2D hip implant models on radiological images or reconstruction of bone, and includes tools for performing measurements on the image or model of bones and for selecting and positioning the implant models. Clinical judgments and experience are required to properly use the software.
Classification and Regulation [Same]	LLZ 892.2050	LLZ 892.2050
Main System Components [Same]	Standalone software	Standalone software
Operational Environment [Same]	RI.HIP MODELER is intended to be used in a clinical setting by a qualified surgeon.	hip EOS is intended to be used in a clinical setting by a qualified surgeon.
Imaging Requirements [Same]	Weight bearing standing and sitting x-ray	Weight bearing standing and sitting x-ray
Image Source [Substantially Equivalent][2]	Images from Brainlab Quentry, iPad Camera Roll, iPad Camera	DICOM
Primary Device Function [Substantially Equivalent][3]	RI.HIP MODELER uses stand-alone software for computer assisted surgical planning. The primary function of the software is to provide a baseline cup orientation recommendation intended to reduce incidences of implant impingement based on inclination/anteversion and implant specifications, and stem anteversion.	hipEOS uses a standalone software for computer assisted surgical planning. The primary function of the software is to provide a recommendation of stem and cup placement intended to reduce incidences of implant impingement, based on inclination/anteversion, implant specifications, stem torsion and localization of the femoral neck resection plane.

[1] *Intended Use/Indications for Use*

RI.HIP MODELER is intended for preoperative planning for primary Total Hip Arthroplasty. RI.HIP MODELER is intended to be used as a tool to assist the surgeon in the selection and positioning of components in primary Total Hip Arthroplasty. RI.HIP MODELER is indicated for individuals undergoing primary Total Hip Arthroplasty.

The indication is substantially equivalent to the indications for use of the predicate, hipEOS (K173390), which is also indicated as a tool to assist healthcare professionals in preoperative planning for Total Hip Arthroplasty. The tools that are included in the predicate device's indications are substantially equivalent to the subject device and compared in the technological characteristic section of the substantial equivalence discussion.

[2] *Image Format*

DICOM images downloaded from Quentry are displayed as a PNG file. RI.HIP MODELER also allows the user to take a picture of an x-ray with the iPad which displays as a PNG file or pull a picture from the camera roll. The software was designed to autodetect and dewarp (if necessary) the specified x-ray. Images can be enhanced using contrast and brightness filters. Additionally, they can be cropped, reset, and retaken. Verification and validation confirmed the camera functionality generated a clinically relevant image with minimal distortion even in worst-case scenario conditions. Training is provided to surgeons on the use of the camera in the application. Human Factors validation confirmed that users could successfully use the camera function to obtain a clinically acceptable image. Validation further showed that those images could be successfully landmarked. The use of the iPad camera to capture an x-ray image does not raise new questions of safety or effectiveness for RI.HIP MODELER.

[3] *Primary Device Function*

RI.HIP MODELER is substantially equivalent to hipEOS in primary function. hipEOS provides a recommendation for both stem and cup placement in the hip. RI.HIP MODELER provides a baseline cup orientation recommendation. The cup recommendation is a subset of the functionality and does not raise new questions of safety or effectiveness for RI.HIP MODELER. Like hipEOS, RI.HIP MODELER uses spinopelvic mobility of the patient to recommend cup inclination/anteversion. hipEOS derives stem torsion based on the 3D model of the patient's anatomy. RI.HIP MODELER allows the user to input stem anteversion based on clinical judgment. Both applications allow the user to adjust stem anteversion. The difference does not raise new questions of safety or effectiveness as the stem torsion is ultimately identified by the qualified healthcare professional.

[4] *Principles of Operation*

RI.HIP MODELER is substantially equivalent to hipEOS in principles of operation. Both devices use standing and sitting x-rays to ascertain the spinopelvic mobility of the patient.

hipEOS reconstructs the patient's anatomy in 3D using frontal and lateral 2D x-rays. The 3D model shows torsion and rotation parameters based on the patient's anatomy. The software provides a baseline stem and cup orientation based on the spinopelvic mobility classification derived from the 3D model and implant specifications.

RI.HIP MODELER employs an algorithm using the determined spinopelvic mobility classification and hip kinematics for typical patient activities of daily living (accessed through a simulation database). Implant kinematics and distance to impingement are calculated for each activity, given a set of implant specifications. The software provides a baseline cup orientation recommendation based on the spinopelvic mobility classification and implant specifications.

The computational models used in the design of RI.HIP MODELER comply with ASME V&V 40: 2018, Assessing Credibility of Computational Modeling through Verification and Validation; Application to Medical Devices and support the algorithm that provides the baseline cup orientation. There are no new questions of safety or effectiveness in using the RI.HIP MODELER to provide a baseline cup orientation as the computational models that support the design have been verified and validated.

[5] *Technological Characteristics*

There are no new concerns for safety or effectiveness associated with the technological characteristics of RI.HIP MODELER.

- RI.HIP MODELER and hipEOS are both standalone software applications with an interactive design that allows the user to overlay 2D x-rays with virtual measuring tools to derive a spinopelvic mobility classification of the patient.
- hipEOS uses a frontal and lateral x-ray to develop a 3D model of the patient's hip. RI. HIP MODELER displays a simulated 3D model of the hip based on the spinopelvic mobility classification. The simulated model is derived from validated computational models that effectively display the range of implant motion in the model.
- The 3D models in both RI.HIP MODELER and hipEOS allow the user to select and overlay implants and view a simulated range of motion.
- RI.HIP MODELER and hipEOS both provide a range of implant motion simulation that allows the surgeon to see how the implant moves in the hip.
- RI.HIP MODELER recommends an acetabular cup placement based on spinopelvic mobility classification. The surgeon selects and compares implants from an application database. hipEOS automatically selects and positions the stem and cup based on 3D reconstruction of the patient anatomy. The surgeon can select and compare the stem and cup from an online database.
- The user can change the inclination/anteversion and stem torsion within the app and visualize the effect of those changes on the 3D model.
- RI.HIP MODELER uses computational modeling in its design that allows a surgeon to view distance to implant impingement through a variety of daily activities of the patient, including, but not limited to, sitting, standing, and walking. hipEOS uses a 3D reconstruction that allows a surgeon to plan implant placement for sitting, standing, and theoretical sitting positions.

- RI.HIP MODELER is an iPad application and hipEOS is a web application. Both devices are standalone software.

There are no new concerns for safety or effectiveness due to the difference in technological characteristics because RI.HIP MODELER was designed to meet its intended use with the technological characteristics within the app. Verification and Validation from Performance Testing confirms that the RI.HIP MODELER is safe and effective and meets its intended use. Performance Testing confirms that representative users of the software application were able to successfully follow the workflow and use the software application in a safe and effective way in the intended use environment.

[6] *User Interface*

RI.HIP MODELER is standalone software that is intended to be installed on an iPad. The predicate device is standalone software that can be installed on any computer. The subject software was verified and validated to ensure specifications were met. User validation showedsurgeons can use the RI.HIP MODELER application safely and effectively on an iPad to plan for total hip arthroplasty procedures. There are no new questions of safety or effectiveness due tothe different interface as the design of RI.HIP MODELER was specific to the intended interface and allows the device to perform its intended use.

Non-Clinical Testing (Bench)

Design verification and validation testing was performed to demonstrate that RI.HIP MODELER meets all design requirements and is as safe and effective as its predicate device. Comprehensive performance testing demonstrated that the subject devices meets the required design inputs. Performance data consisted of physical performance test for all the software application. Additionally, the following test data was provided:

- **Software Verification Testing**, including software integration and workflow testing, was completed. Software was developed in accordance with *IEC 62304 Medical Device Software - Software Life Cycle Processes*, and this submission contains documentation per the requirements of FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

- **Image Capture Verification Testing** was completed to ensure worst case image capture would not produce distorted images that would affect clinical measurements. Testing demonstrated that even in worst-case conditions accuracy of landmarking measurements was within 2 degrees.

- **Usability Engineering Validation Testing** was completed demonstrating that representative users were able to safely and effectively use RI.HIP MODELER in a simulated use environment.

No human clinical testing was required to determine the safety and effectiveness of RI.HIP MODELER.

Conclusion

The subject device, RI.HIP MODELER, described in this submission has a similar intended use and primary device function as the predicate device, hipEOS (K173390). The primary difference between the two devices is that RI.HIP MODELER uses 2D x-rays and an algorithm based on computational modeling to determine a baseline acetabular cup placement while hipEOS uses a 3D model of the patient derived from a compilation of x-rays to determine stem and cup placement. The differences do not raise any new questions of safety or effectiveness.

The key determining factor in establishing substantial equivalence is whether RI.HIP MODELER can provide a baseline cup orientation that increases distance to implant impingement during activities of daily living, thereby reducing the risk of implant impingement. The results of verification and validation indicate that there are no safety or performance concerns and that RI.HIP MODELER meets its intended use. The usability testing results for Human Factors demonstrate that representative users are able to use the subject device safely and effectively to meet the desired intended use. The information presented in this 510(k) premarket notification demonstrates that RI.HIP MODELER is as safe and effective as the predicate hipEOS system (K173380). Blue Belt Technologies believes that RI.HIP MODELER is substantially equivalent to the predicate device.