JointVue LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

November 15, 2017

Re: K173329
Trade/Device Name: jFit Surgical Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 19, 2017
Received: October 23, 2017

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K173329

Device Name
jFit Surgical Planner

Indications for Use *(Describe)*
JointVue's jFit Surgical Planner is a software device intended to assist medical professionals in preoperative planning of orthopedic surgery. The device allows for overlaying templates of prostheses on 3D bone models generated from radiological images. The software includes tools for performing measurements on the images and for positioning the prosthetic template. Clinical judgment and experience are required to properly use the software.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

JointVue LLC
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Tel: (877) 725-6920 x101
Fax: (865) 539-8136

Contact Person: Mohamed R. Mahfouz
Title: President/CEO
Date Prepared: November 1, 2017

II. DEVICE

Name of Device:	jFit Surgical Planner
Classification Name:	Picture Archiving and Communications System
Regulation:	21 CFR §892.2050
Regulatory Class:	Class II
Product Classification Code:	LLZ

III. PREDICATE DEVICE

Predicate Manufacturer:	Orthocrat, Ltd.
Predicate Trade Name:	TraumaCAD 2.0
Predicate 510(k):	K073714

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

JointVue's jFit Surgical Planner is an orthopedic preoperative planning software. It allows for overlaying templates of prostheses on patient 3D bone models generated from radiological images using JointVue's 3D echo software (K172513) for overlaying templates of prostheses for surgical preplanning of joint replacement surgery.

jFit Surgical Planner is intended to run on a PC and requires the Microsoft Windows™ operating system, version 7, windows 8 or windows 10 (32-bit/64-bit). A PDF Reader such as Adobe Acrobat or Foxit is recommended in order to access the instructions for use. jFit Surgical Planner software requires the following minimum requirements for computer hardware listed in the following table:

Hardware Requirements for jFit Surgical Planner	
Processor	Intel Core i5-5300 @ 2.3 GHz or higher
Memory	8 GB RAM or more
Graphics	Intel HD Graphics 5500 or higher
Resolution	Minimum 1920*1080
HD Space	1 GB or more

The major functions and features of jFit Surgical Planner include:

1. Patient Case Loading
2. Loading X-Ray Images
3. Editing and Verifying Femur Landmarks
4. Editing and Verifying Tibia Landmarks
5. Conducting Femur Planning
6. Conducting Tibia Planning
7. Validating Surgical Planning
8. Generation of a Surgical Planning Summary Report

jFit Surgical Planner is for installation on a secure computer workstation to protect patient data. Typical environment of use is an office environment.

jFit Surgical Planner utilizes 3D bone models for preoperative planning of joint replacement surgery. Surgical preplanning starts by importing patient 3D bone models along with anterior-posterior and lateral X-Ray images, if available. jFit Surgical Planner calculates relevant surgical landmarks which can then be verified and edited. jFit Surgical Planner will suggest an initial implant selection and placement based on anatomical landmarks selected and verified by the clinician. The clinician is responsible to adjust the implant selection and placement parameters to validate patient-specific surgical plan. Upon completion of surgical planning, a summary report is generated that must be signed by a physician to approve the surgical plan.

V. INDICATIONS FOR USE

JointVue's jFit Surgical Planner is a software device intended to assist medical professionals in preoperative planning of orthopedic surgery. The device allows for overlaying templates of prostheses on 3D bone models generated from radiological images. The software includes tools for performing measurements on the images and for positioning the prosthetic template. Clinical judgment and experience are required to properly use the software.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Intended Use / Indications for Use – The predicate device and the subject device have identical intended use and the only difference in the indications for use is that the jFit Surgical Planner uses patient 3D bone models generated from radiological images (K172513) rather than overlaying templates of prostheses directly on native radiological images for surgical preplanning of joint replacement surgery.
- Materials – Not applicable, because both are software devices and do not have patient contact.
- Design Features – The predicate and subject device design features are summarized in comparison Table 5-1.
- Energy Source – The predicate and subject device are both operated on a PC computer via battery or mains power.
- Performance Testing – The predicate and subject device have equivalent precision and accuracy based on benchtop testing.

Table 5-1

Feature	**Subject Device (jFit Surgical Planner)**	**Predicate Device (TraumaCAD 2.0)**
Computer Operating System	Windows 7, 8 or 10	Windows 7
2D Image Display Axial Sagittal Coronal Oblique	 Yes Yes Yes Yes	 Yes Yes Yes Yes
3D Visualization	Yes (Surface Visualization)	Yes (Volumetric Visualization)
View Mode Render	Yes (Display Axial image with 3D visualization)	Yes (Display Axial image with 3D image)
Contouring	Yes	Yes

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Not Applicable to the subject device, because the device is stand-alone software.

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable to the subject device, because the device is stand-alone software.

Software Verification and Validation Testing

Software verification and validation testing was provided to demonstrate safety and efficacy of the subject device. This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern (LOC). Software validation documentation provided to demonstrate that the software design specification (SDS) meets the software requirements specification (SRS) includes:

- Software description
- Hazard Analysis
- Software requirements specification (SRS)
- Software Architecture Description
- Traceability Matrix
- Software Development Environment Description
- Software Verification Test Description
- Revision Level History
- Unresolved Anomalies
- Procedure for Software Development Lifecycle
- Software Verification Test Protocol
- Software Verification Test Report
- Cybersecurity Risk Analysis

Mechanical and Acoustic Testing
Not Applicable to the subject device, because the device is stand-alone software.

Bench Top Testing
Side by side testing was performed between the predicate and subject device to confirm equivalent safety and efficacy. Testing consisted of performing femoral and tibial implant sizing with the predicate device and the subject device on 39 simulated cases. Testing was completed by two independent users, and the case ID was blinded for both operators. Both the predicate and the subject device identified the same size implants in 100% of the simulated cases.

Animal Study
Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies
Clinical testing was not required to demonstrate the safety and effectiveness of the jFit Surgical Planner. This conclusion is based upon a comparison of intended use, technological characteristics and benchtop testing.

VIII. CONCLUSIONS
The subject device is equivalent to the predicate device with regard to safety and efficacy. This conclusion is based upon a comparison of intended use, technological characteristics and benchtop testing.