Intellijoint Surgical Inc.
℅ Katarina Jugovic
Regulatory Affairs Associate
809 Wellington Street North, Unit 2
Kitchener, Ontario N2H 5L6
CANADA

November 12, 2021

Re: K211876
Trade/Device Name: Intellijoint VIEW
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 14, 2021
Received: October 15, 2021

Dear Katarina Jugovic:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211876

Device Name
Intellijoint VIEW

Indications for Use *(Describe)*
Intellijoint VIEW is indicated to assist qualified healthcare professionals in preoperative planning and postoperative review of orthopedic surgery. The device allows for orthopedic implant templates to be overlaid on medical images for the purpose of selecting and positioning implants. The device includes tools for performing measurements and evaluating surgical treatment options. Clinical judgement 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.

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510(k) Summary

1. Submitter Information

Submitter: **Intellijoint Surgical Inc.**
Address: 809 Wellington St. N., Unit 2
Kitchener, ON
Canada N2H 5L6

Telephone: (519) 342–3178
Fax: (226) 317–0471

Contact: Andrew Graham

Date Prepared: 7 Oct 2021

2. Device Information

Trade Name: Intellijoint® VIEW
Common Name: Medical Image Management and Processing System
Classification: Class II per 21 CFR 892.2050
Product Code: LLZ

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new software as a medical device, Intellijoint® VIEW.

4. Predicate Device Information

The Intellijoint® VIEW product described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
TraumaCAD (primary)	OrthoCrat Ltd	K042816
Cuptimize	Cuptimize, Inc.	K203651

5. Device Description

Intellijoint® VIEW is a web-based software as a medical device (SaMD) product that assists health care professionals complete preoperative planning and postoperative review for orthopedic surgery. Preoperative planning on Intellijoint® VIEW involves the user completing measurements on medical images to inform the selection and intraoperative positioning of orthopedic implant system components. Intellijoint® VIEW also allows for postoperative image review and measurement.

Intellijoint® VIEW Templating tool allows the user to perform distance and angular measurements on scaled medical images, to inform selection of acetabular and femoral implant components.

Intellijoint® VIEW Hip-Spine Assessment allows the user to assess a patient's spinopelvic relationship for preoperative functional acetabular cup position planning. The Application overlays acetabular measurement tools on standing and sitting lateral functional patient images to inform an appropriate implant position based on the functional relationship between the hips and spine.

6. Indications for Use

Intellijoint VIEW is software indicated to assist qualified healthcare professionals in preoperative planning and postoperative review of orthopedic surgery. The device allows for orthopedic implant templates to be overlaid on medical images for the purpose of selecting and positioning implants. The device includes tools for performing measurements and evaluating surgical treatment options. Clinical judgement and experience are required to properly use the software.

7. Comparison of Technological Characteristics

The substantial equivalence of Intellijoint® VIEW to the predicates is shown by similarities in intended use, indications for use, and performance.

Property	**Intellijoint® VIEW**	**Primary Predicate** TraumaCAD (K042816)	**Predicate 2** Cuptimize (K203651)
510(k) No.	K211876	K042816	K203651
Classification	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ	LLZ; HAW

Property	Intellijoint® VIEW	Primary Predicate TraumaCAD (K042816)	Predicate 2 Cuptimize (K203651)
Indications for Use	Intellijoint VIEW is indicated to assist qualified healthcare professionals in preoperative planning and postoperative review of orthopedic surgery. The device allows for orthopedic implant templates to be overlaid on medical images for the purpose of selecting and positioning implants. The device includes tools for performing measurements and evaluating surgical treatment options. Clinical judgment and experience are required to properly use the software.	The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning or orthopedic surgery. 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 judgements and experience are required to properly use the software.	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.
Versions	Web version	Client/server version Standalone version Web version	Web version
Computer	PC and MAC Compatible Not for use on mobile phones Not tablet compatible	PC and MAC Compatible Not for use on mobile phones iPad compatible	PC and MAC Compatible Not for use on mobile phones
Operating Systems	MacOS Windows	MacOS Windows	MacOS Windows
Anatomical Locations	Hip	Hip, Knee, Upper Limb, Foot and Ankle, Trauma, Spine, Pediatric, Deformity, 3D Suite	Hip
Image Input	2D radiographs	2D radiographs	2D radiographs
Image Measurements	Templating		
	Leg Length Discrepancy	Leg Length Discrepancy	N/A

Property	Intellijoint® VIEW	Primary Predicate TraumaCAD (K042816)	Predicate 2 Cuptimize (K203651)
	Hip-Spine Assessment		
	Angular measurements (Inclination Reference, Pelvic Tilt, Sacral Slope, Pelvic Incidence, Lumbar Lordosis, Pelvic Incidence-Lumbar Lordosis mismatch)	Angular measurements	Angular measurements (Inclination Reference, Pelvic Tilt, Sacral Slope, Pelvic Incidence, Spinopelvic Tilt Angle)
Output Data	Templating		
	Selected Implants Anticipated anatomical changes (Leg Length, Offset, Femoral Stem Positioning, Acetabular Cup Position)	Selected Implants Anticipated anatomical changes (Leg Length, Offset, Femoral Stem Positioning, Acetabular Cup Position)	N/A
	Hip-Spine Assessment		
	Anatomical measurements (Pelvic Tilt, Sacral Slope, Pelvic Incidence, Lumbar Lordosis, Pelvic Incidence-Lumbar Lordosis mismatch) Target Cup Position (Inclination and Anteversion)	N/A	Anatomical measurements Target Cup Position (Inclination and Anteversion)
Software Features	Templating		
	Template overlay capability, Interactive template positioning, Image Scaling, Template support from manufacturers, Permits template rotation	Template overlay capability, Interactive template positioning, Image Scaling, Template support from manufacturers, Permits template rotation	N/A
	Hip-Spine Assessment		
	Preoperative cup position analysis.	N/A	Preoperative and intraoperative cup position analysis.

8. Performance Data

The following tests were performed to demonstrate the substantial equivalence of Intellijoint® VIEW to its predicate devices:

Test	Summary	Result
Verification		
Software Functional and Unit Tests	Verified that Intellijoint® VIEW satisfies functional requirements and performs as intended. Algorithms and measurement calculations were verified in these tests.	Software satisfied all requirements and specifications.
Accuracy Test	Provides confirmation that distance and angular measurements satisfy requirements for accuracy. Provides confirmation that implant templates are displayed correctly and accurately.	Software satisfied all accuracy requirements.
Validation		
Simulated Use and Usability Validation	Simulated use testing was performed by qualified orthopedic surgeons on radiographic images following a typical workflow. This test validated that Intellijoint® VIEW satisfies user needs and intended use.	All user needs were met.

The testing demonstrated that the Intellijoint® VIEW is substantially equivalent to the legally marketed predicate devices for its intended use.

Non-Clinical Testing

Non-clinical testing was performed to assess the safety and effectiveness of the device, to demonstratethat themeasurement tools produced accurate, repeatable, and reproducible implant selection, sizing,and placement of components. Testing verified that the software application is operating according to specified design requirements. Intellijoint VIEW displays angular measurements to within ± 0.8°and distance measurements to within ± 0.3 mm of their true value. Distance measurements of resultant position changes due to implant placement, are displayed to within ± 1 mm of their true value. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate devices.

Software testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software as a Medical Device". The software application was of "moderate" level of concern because a failure or latent flaw in the software could indirectly result in minor injury to the patient through incorrect or delayed information.

Clinical Testing

Clinical testing was not necessary for this Traditional 510(k).

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate devices, Intellijoint® VIEW has been shown to be substantially equivalent to the legally marketed predicate devices identified in this submission and does not present any increased risk to safety or effectiveness.

Based on the information supplied in this 510(k), it is our conclusion that our device is safe, effective, and substantially equivalent to the primary predicate device.