June 8, 2026

One Ortho
Theo Vidal
Operations Manager
Parc Inopolis
206 Rte. De Vourles
Saint-Genis-Laval, 69230
France

Re: K261352
Trade/Device Name: 2D Hip Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 24, 2026
Received: April 24, 2026

Dear Theo Vidal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261352 |

Please provide the device trade name(s).

2D Hip Planning Software

Please provide your Indications for Use below.

The 2D HIP PLANNING SOFTWARE is indicated for assisting orthopedic surgeons in preoperative planning of primary hip replacement orthopedic surgery. The device allows for overlaying 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary K261352

# Device: 2D Hip Planning Software

| | |
|---|---|
| **Applicant/Manufacturer:** | One Ortho |
| **Company Address:** | Parc Inopolis, 206 Route de Vourles Saint-Genis-Laval, France 69230 |
| **Contact Person:** | Theo Vidal, Phone: 33 (4) 26 78 76 74 |
| **Date Summary Prepared:** | April 21, 2026 |
| **Trade Name:** | 2D Hip Planning Software |
| **Classification Name:** | Medical image management and processing system |
| **Product Code:** | LLZ (System, Image Processing, Radiological) |
| **Device Class:** | Class II |
| **Regulation Number(s):** | 21 CFR 892.2050 |

## 1. Device Description

The 2D Hip Planning Software is a web-based software for orthopedic surgeons to perform preoperative planning for hip replacement procedures. It provides tools/functionalities for the user to load and view patient 2D frontal hip radiological images upon which they can overlay and position model outlines of available hip replacement cup and stem components according to the patient's bony features as depicted by the 2D images. This allows them to pre-operatively estimate the sizes of the components and to preview their surgical placement.

## 2. Predicate Information

| Trade name | Predicate: TraumaCad Mobile Release 2.0 |
|---|---|
| **510(k)** | K160001 |
| **Manufacturer** | Brainlab AG<br>(originally by Voyant Health Ltd.) |
| **Class** | II |
| **Product Code / Name**<br>**Classification Regulation / Name** | LLZ / System, Image Processing, Radiological<br>892.2050 / Medical image management and processing system |

## 3. Comparison of intended use - indications for use

As shown in the table below, the 2D Hip Planning Software intended use and indications are the same as in the predicate with the exception that the 2D Hip Planning Software indication is limited to the planning of primary total hip replacement procedures while the labelled predicate indication is wider for the planning of a multitude of orthopedic procedures including total hip replacement, total knee replacement, foot & ankle procedures, and upper limb procedures. In addition, the predicate includes a mobile version of the software for use on an iPad portable device but with the restriction for it not to be used on a mobile phone. This restriction is not applicable in the 2D Hip Planning Software since it does not offer a mobile version. As will be further described in the next technological comparison section, the predicate 510(k)

includes a web-based version as in the subject 2D Hip Planning Software. The indications of the 2D Hip Planning Software are therefore within that of the predicate and are therefore substantially equivalent.

| 2D Hip Planning Software | Predicate<br>TraumaCad Mobile Release 2.0 |
|---|---|
| The 2D HIP PLANNING SOFTWARE is indicated for assisting orthopedic surgeons in preoperative planning of primary hip replacement orthopedic surgery. The device allows for overlaying 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 TraumaCad Mobile Release 2.0 program is indicated for assisting healthcare professionals in preoperative planning of 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 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. |

## 4. Comparison of Technological Characteristics

The main technological methods and functionalities are compared below between the 2D Hip Planning Software and the predicate.

| | 2D Hip Planning Software | Predicate<br>TraumaCad Mobile Release 2.0 |
|---|---|---|
| **Main method of operation** | Display of 2D frontal hip X-ray images with tools for the user to overlay and position model outlines of given hip replacement components on the images according to the patient's bony features depicted by the 2D images | **Same**<br>Display of 2D frontal hip X-ray images with tools for the user to overlay and position model outlines of given hip replacement components on the images according to the patient's bony features depicted by the 2D images<br><br>TraumaCAD also provides an optional 3D Suite for 3D templating which is not applicable for 2D Hip Planning Software. |
| **Procedure types** | Total hip replacement | **Same**<br>Total hip replacement,<br><br>Also provides modules for additional orthopedic procedures:<br>total knee replacement, foot & ankle procedures, and upper limb procedures, and Spine procedures – these are not applicable for 2D Hip Planning Software. |

| | 2D Hip Planning Software | Predicate<br>TraumaCad Mobile Release 2.0 |
|---|---|---|
| **Compatible radiographic images** | X-ray images | **Same**<br>X-ray images |
| **X-Ray Image Calibration** | Manual or automatic calibration per automatic detection of calibration ball in X-ray | **Same**<br>Manual or automatic calibration per automatic detection of calibration ball in X-ray<br>Also allows calibration by automatic detection of Kingmark calibration device in X-ray. |
| **Available Implant Models** | User selects the hip implant cup and stem models and sizes from a list of implant systems integrated in the software as provided by the implant manufacturers | **Same**<br>User selects the hip implant cup and stem models and sizes from a list of implant systems integrated in the software as provided by the implant manufacturers |
| **Tolls to move/rotate implant schematics on the X-ray** | Graphical tools to translate and rotate the implant schematic overlay on the X-ray images | **Same**<br>Graphical tools to translate and rotate the implant schematic overlay on the X-ray images |
| **Femoral Resection Line (head osteotomy resection line) and corresponding displacement of femur** | Tools to draw the femoral resection line upon which the stem's shoulder will be seated against, and to automatically reposition the femur segment on the X-ray with the correspondingly seated femoral stem (femoral head center and acetabulum center are made coincident). | **Similar**<br>Similarly provides tools to draw the femoral resection line upon which the stem's shoulder will be seated against, and to automatically reposition the femur segment on the X-ray with the correspondingly seated femoral stem (femoral head center and acetabulum center are made coincident). The difference is that the predicate automatically identifies a suggested resection line which the user may modify. |
| **Measurement functions** | Distance and angle measuring tools<br>Circle tool to measure diameter | **Same**<br>Distance and angle measuring tools<br>Circle tool to measure diameter |
| **Leg length and offset** | Automatic calculation of leg length and offset (medial/lateral) changes according to the placement of the implants | **Same**<br>Automatic calculation of leg length and offset (medial/lateral) changes according to the placement of the implants |

| | 2D Hip Planning Software | Predicate<br>TraumaCad Mobile Release 2.0 |
|---|---|---|
| **Additional Tools** | Two possible planning methods:<br>- Free mode: the stem and cup are initially placed in the center of the image for the surgeon to position them using the placement tools.<br>- Advanced mode (auto placement mode): The software automatically positions and orients the selected stem and cup on the X-ray image according to the diaphyseal axis approximated by surgeon identified landmarks of the medular cavity for the stem location, and the sizing and location of the acetabulum using the circle tool for the cup location. The user thereafter further finetunes the placement of the components as needed using the placement tools. | **Differences**<br>Optional automated planning and assessment tools:<br>- Auto-Hip: automatic placement of components per the identification of user defined landmarks using the given wizard tool. This includes initial placement of the cup and stem components in the medular cavity along the diaphyseal axis and in the acetabulum.<br>This tool has equivalent features as the Advanced Mode in the proposed 2D Hip Planning Software.<br>The predicate also includes tools for the assessment of general hip orthopedic characteristics other than the pre-operative positioning of hip implant templates and that are outside the scope of the 2D Hip Planning Software. These include tools for post-operative measurements, hip deformity parameter measurements, leg length discrepancy measurements, and VCA angle of Lequesne measurements. |
| **Report** | PDF report files presenting the validated plan with the sizes and model information of the planned prosthesis and 2D visualization of the prosthesis template upon the patient's hip X-Ray image. | **Same**<br>PDF report files presenting the validated plan with the sizes and model information of the planned prosthesis and 2D visualization of the prosthesis template upon the patient's hip X-Ray image. |
| **Client/Server, Standalone Or Web** | Web access | **Same**<br>Web access<br>Additional client/server, standalone, or mobile use |
| **Compatible Operating System** | Operating system: Windows, Mac OS | **Same**<br>Operating system: Windows, Mac OS |

The 2D Hip Planning Software utilizes the same main technological means and provides the same main tools/functionalities as the predicate to provide its intended use (hip prosthesis X-ray templating). The main departures between the 2D Hip Planning Software and the predicate is that the predicate involves numerous additional modules as well as a 3D Suite to perform procedures other than the 2D total hip templating as intended in the 2D Hip Planning Software, and that, within the module for the common 2D

total hip templating procedure, the predicate also involves additional tools that are for the assessments of given general hip characteristics not directly used to position hip component templates on X-ray images. These additional tools are outside the scope of the 2D Hip Planning Software. The main tools in the 2D Hip Planning Software as used to move and orient the stem or cup hip implant components on the patient's pre-operative X-Ray are the same or similar as in the predicate with similar automation features including the initial placement of the stem and cup components respectively in the medullar cavity along the diaphyseal axis and in the acetabulum.

## 5. Performance Testing:

The 2D Hip Planning Software has been verified and validated to ensure its functionalities perform as required to meet its intended use as follows:

- Software verification and validation tests and evaluations were performed in accordance with IEC 62304 and FDA Guidance documents, "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".
- Bench tests were conducted to ensure adequate measurement tool accuracy performance within ± 1 mm for distances and ± 0.1 deg for angles.
- Implant Size Accuracy Performance was validated per a post market clinical study in the EU (n=199 patients) that demonstrated that the implant sizing accuracy can be expected to be within ± 1 size in at least 75% of cases, and within ± 2 sizes in at least 90% of cases.

## 6. Conclusion

The 2D Hip Planning Software has the same total hip X-ray templating intended use and indication as the predicate and involves the same main methods and technology. Performance testing and validation demonstrated that the 2D Hip Planning Software is safe and effective as the predicate. In conclusion, the 2D Hip Planning Software is found to be substantially equivalent to the predicates.