



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Voyant Health, Ltd.  
% Mr. Yael Guttentag  
QM&RA Manager  
35 Eyal Street  
Petach-Tikva 4951132  
ISRAEL

February 12, 2016

Re: K160001  
Trade/Device Name: Traumacad Mobile Release 2.0  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: January 25, 2016  
Received: January 29, 2016

Dear Mr. Guttentag:

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 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 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 yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

## Indications for Use

510(k) Number (if known)

K160001

Device Name

TraumaCad Mobile Release 2.0

Indications for Use (Describe)

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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

- 1. Submitter's (a) Address:** Yael Guttentag  
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35 Efal Street  
Petach-Tikva  
Israel, 4951132
  
- 1. Manufacturer (b) Address:** Voyant Health, Ltd.  
35 Efal Street  
Petach-Tikva  
Israel, 4951132

**Mfg. Phone:** 972-3-929-0929

**Mfg. Fax:** 972-3-923-6413

**Contact Person:** Yael Guttentag, QM&RA Manager

**Date:** Dec 29, 2015
  
- 2. Device & Classification Name:** Imaging Processing System (Class 2), Product Code LLZ, 21 CFR 892.2050  
Trade name of device: TraumaCad Mobile Release 2.0
  
- 3. Predicate Device:** TraumaCad Release 2.0 (K073714)  
TraumaCad Mobile Release 1.0 (K142923)
  
- 4. Description:** TraumaCad Mobile Release 2.0 allows surgeons to evaluate digital images while performing various pre-operative surgical planning and evaluation of images. This software application enables surgeons to plan operations on screen, execute measurements, and facilitate the film-less orthopedic practice. The program features full PACS integration and an extensive regularly updated library of digital templates from leading manufacturers. TraumaCad Mobile Release 2.0 supports DICOM and enables the importing and exporting of image files

from a central PACS system, or Qentry (Class I device registered by Brainlab AG in the FDA).

TraumaCad Mobile Release 2.0 has the same intended use as TraumaCad Mobile Release 1.0 (K142923 cleared by the FDA on March 5, 2015) and the same basic features as predicate device TraumaCad Release 2.0 (K073714 cleared by the FDA on March 19, 2008). Three new procedures have been added, Knee, Upper Limb, and Foot&Ankle to the predicate device TraumaCad Mobile Release 1.0. These procedures exist in the predicate device TraumaCad 2.0. This allows pre-operative planning in these areas, as well as the previously cleared Hip procedure. In addition, TraumaCad Mobile Release 2.0 has the ability to open more than one image at a time, similar to the predicate device TraumaCad 2.0.

TraumaCad Mobile Release 2.0 is the web based version of the predicate device TraumaCad 2.0 (cleared by the FDA on March 19, 2008). The TraumaCad Mobile Release 2.0 has the same basic functionality as the predicate device, but is now available as a web based version on additional platforms. The differences between the device and the predicate device do not impact on substantial equivalence.

TraumaCad Mobile Release 2.0 is a web based device that can be used on PCs, Mac, or iPad 3, 4 or 5 (Air) and interacts with a PACS system or Qentry. No installation is required. TraumaCad Mobile Release 2.0 provides web based access and should only be used on computers and iPads that are already qualified for wireless use in a clinical setting. TraumaCad Mobile Release 2.0 is not intended for use on mobile phones. Use of TraumaCad Mobile Release 2.0 for planning on a tablet is not to replace planning on a workstation. Use on a tablet is only for situations when a workstation is not available.

In order to access TraumaCad Mobile, the user needs to browse to a specific URL and enter the system via username and password. A Web Application is available in the iTunes store that will automatically open the browser with the correct URL. The application can be downloaded from iTunes for free but cannot be used without receiving a license to ensure the

use by appropriate healthcare professionals.

The program features full PACS integration and an extensive regularly updated library of digital templates from leading manufacturers. TraumaCad Mobile Release 2.0 supports DICOM and enables the importing and exporting image files from a central PACS system or from Qentry.

- 5. Intended Use:** 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.
- 6. Conclusion** The successful non-clinical testing demonstrates the safety and effectiveness of the TraumaCad Mobile Release 2.0 when used for the defined indications for use and demonstrates that these devices for which this 510(k) is submitted perform as well as or better than the legally marketed predicate device.

TraumaCad Mobile contains a subset of the features from TraumaCad 2.0. The algorithms contained on TraumaCad Mobile are the same as those that are in the predicate device TraumaCad 2.0 that have been extensively tested.

The testing for each release consisted of Unit, System/Integration and Acceptance test levels. Testing included security, negative testing, error message handling, stress testing, platform testing, workflow testing, functional testing, multi-user/external access testing, data integrity testing, compatibility testing, load testing, regression testing, and hazard mitigation testing.

In case a test was failed any necessary corrections were made, the relevant test was executed and repeated again until all passed.

**7. Changes to Predicate Device**

TraumaCad Mobile Release 2.0 is the same as the TraumaCad Mobile Release 1.0 with the addition of three new procedures, Knee, Upper Limb, and Foot&Ankle. This allows pre-operative planning in these areas, as well as the previously cleared Hip procedure. These procedures exist already in the predicate device TraumaCad 2.0 and they have been added to the TraumaCad Mobile Release 2.0.

In TraumaCad Mobile Release 1.0 only the Hip procedure was implemented. In TraumaCad Mobile Release 2.0 the following procedures have been added.

- Knee – Knee procedure is aimed to provide the users with a method to perform Total Knee Replacement (TKR), including evaluation of resection line, positioning of implant templates and auto alignment, for AP and LAT images.
- Foot&Ankle – Foot&Ankle procedure allows positioning of specific Foot&Ankle implant templates on the image
- Upper Limb – Upper Limb procedure allows positioning of specific Upper Limb implant templates on the image

Multiple Images – In the predicate device TraumaCad Mobile Release 1.0, only one image could be opened at a time. TraumaCad Mobile Release 2.0 supports opening of up to two images. This functionality already exists in the predicate device TraumaCad 2.0, which can open up to 4 images at a time.

**8. Comparison of Technological Characteristics:**

TraumaCad Mobile Release 2.0 has the same intended use and risk control measures as the predicate device TraumaCad Mobile Release 1.0. TraumaCad Mobile Release 2.0 contains a limited feature set in comparison to the predicate device TraumaCad 2.0. The features in TraumaCad Mobile already exist in the predicate device TraumaCad but have been modified to run on new platforms. Thus we revisited our risk analysis to consider any new potential failure modes and causes for hazards intrinsic to the new mobile environment and implemented new risk control measures as necessary.

Testing was done to compare TraumaCad Mobile with the predicate device TraumaCad 2.0 using various medical images from a range of cases in parallel and comparing TraumaCad 2.0 on a PC device and TraumaCad Mobile on an iPad device. Testing included the main functions such as: Marker detection,

Calibration result and Templates positioning. The test shows that the predicate device TraumaCad 2.0 and TraumaCad Mobile have the same expected results in all of the tests.

In addition, usability testing was performed using mobile devices and PC environments. The Usability testing simulated a clinical environment and required the test participant to perform preoperative planning on various Hip X-rays in a manner that is almost identical to the planning done on the predicate device. Most of the test participants had used the predicate device TraumaCad 2.0 in the past and were familiar with the workflow in the predicate device.

The primary operating functions (which exist in the predicate device as well) were tested in a clinical environment and include:

- Select an x-ray image from Qentry/PACS
- Calibrate the image
- Select implants
- Evaluate LLD and offset changes
- Change the implant properties accordingly
- Use measurement tools
- Save the results back to Qentry/PACS

Additional Usability testing was done on the Knee procedure of TraumaCad Mobile Release 2.0 in order to simulate a clinical environment. Various knee images were used and multiple templates placed on the images.

The primary operating functions were tested in a clinical environment and include:

- Select the relevant clinical procedure
- Calibrate the Knee x-ray image
- Select implants – femoral and tibial components
- Change the implant properties
- Evaluate the resection line and mechanical and anatomical axis.
- Perform Auto Alignment

Based on the above testing and updated risk analysis, the differences between the device and the predicate devices do not impact on substantial equivalence.



Parameter/Character	Subject Device TraumaCad Mobile 2.0	Predicate Device TraumaCad Mobile 1.0	Predicate Device TraumaCad 2.0
Operating System	MS Windows 7, 8 or 10 iOS 7.x, 8.x or 9.x Mac OS X	MS Windows 7 iOS 6.1 or 7.x Mac OS X	Windows/PC MS Windows 2000 or later
Devices supported	PC/MAC iPad 3, 4 and 5 (Air)	PC/MAC iPad 3, 4 and 5 (Air)	PC
Browsers supported	<b>Minimum requirements:</b> <b>iOS based browsers:</b> - Safari 7 - Chrome 30 <b>Mac based browsers:</b> - Firefox 26 - Safari 5 <b>Windows based browsers:</b> - Chrome 30 - Firefox 26 - Safari 5 - IE 11	<b>Minimum requirements:</b> <b>iOS based browsers:</b> - Safari 7 - Chrome 30 <b>Mac based browsers:</b> - Firefox 26 - Safari 5 <b>Windows based browsers:</b> - Chrome 30 - Firefox 26 - Safari 5 - IE 11	NA
Image Input	Can receive digital images from various sources	Can receive digital images from various sources	Can receive digital images from various sources
Means of Collecting Data	Obtained from pre-obtained digital images via PACS system or via Query	Obtained from pre-obtained digital images via PACS system or via Query	Obtained from pre-obtained digital images via PACS system

Parameter/Character	Subject Device TraumaCad Mobile 2.0	Predicate Device TraumaCad Mobile 1.0	Predicate Device TraumaCad 2.0
Number of Images that can simultaneously viewed on screen	Up to Two	One	Up to 4
Runs on Server	Yes	Yes	Yes
Hip Module	Yes	Yes	Yes
Trauma Module	No	No	Yes
Knee Module	Yes	No	Yes
Spinal Module	No	No	Yes
Pediatric Module	No	No	Yes
Foot & Ankle Module	Yes	No	Yes
Upper Limb Module	Yes	No	Yes
Input 3D Images	No	No	Yes
Digital Prosthetic Templates	Yes	Yes	Yes
Interactive template positioning	Yes	Yes	Yes
Automatic Scaling	Yes	Yes	Yes
Template support from manufacturers	Yes	Yes	Yes
Permits template rotation	Yes	Yes	Yes
Pre-operative Planning	Yes	Yes	Yes
Patient Contacting	No	No	No
Control of Life-Saving Devices	No	No	No
Healthcare professionals intervention for interpretation and manipulation of images	Yes	Yes	Yes
510(k) #	Pending	K142923	K073714