DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 08, 2015

Voyant Health Ltd.
% Mrs. Yael Guttentag
QM&RA Manager
35 Efal Street
Petach-Tikva 4951132
ISRAEL

Re: K142923
Trade/Device Name: TraumaCad Mobile Release 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 26, 2015
Received: January 28, 2015

Dear Mrs. Guttentag:

This letter corrects our substantially equivalent letter of March 5, 2015.

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.

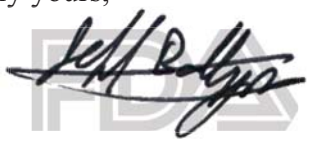
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K142923

Device Name
TraumaCad Mobile Release 1.0

Indications for Use *(Describe)*
The TraumaCad Mobile Release 1.0 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)*

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

510(k) Summary

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

1. (a)	**Submitter's Address:**	Yael Guttentag Voyant Health, Ltd. 35 Efal Street Petach-Tikva Israel, 4951132
1. (b)	***Manufacturer 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:	March 4, 2015
2.	***Device & Classification Name:***	Imaging Processing System (Class 2), Product Code LLZ, 21 CFR 892.2050 Trade name of device: TraumaCad Mobile Release 1.0
3.	***Predicate Device:***	TraumaCad Release 2.0 (K073714)
4.	***Description:***	TraumaCad Mobile Release 1.0 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 1.0 supports DICOM and enables the importing and exporting of image files from a central PACS system, or Quentry (Class I device

Voyant HEALTH™
a Brainlab Company

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

registered by Brainlab AG in the FDA).

TraumaCad Mobile Release 1.0 is the web based version of the predicate device TraumaCad 2.0 (cleared by the FDA on March 19, 2008). The TraumaCad Mobile Release 1.0 has the same basic functionality and intended use 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 1.0 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 Quentry. No installation is required. TraumaCad Mobile Release 1.0 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 is not intended for use on mobile phones. Use of TraumaCad Mobile 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 will be 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 supports DICOM and enables the importing and exporting image files from a central PACS system or from Quentry.

5. ***Intended Use:*** The TraumaCad Mobile Release 1.0 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

Voyant HEALTH™
a Brainlab Company

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

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 1.0 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. *Comparison of Technological Characteristics:*

TraumaCad Mobile 1.0 has the same intended use and risk control measures as the predicate device TraumaCad 2.0. TraumaCad Mobile contains a limited feature set in comparison to the predicate device TraumaCad. 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 using various medical images from a range of cases in parallel and comparing TraumaCad 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 and TraumaCad Mobile

Voyant HEALTH™
a Brainlab Company

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

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

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

Parameter/Character	Subject Device TraumaCad Mobile 1.0	Predicate Device TraumaCad 2.0
Operating System	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

Voyant HEALTH™
a Brainlab Company

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

Parameter/Character	Subject Device TraumaCad Mobile 1.0	Predicate Device TraumaCad 2.0
Browsers supported	**Minimum requirements:** **iOS based browsers:** - Safari 7 - Chrome 30 **Mac based browsers:** - Firefox 26 - Safari 5 **Windows based browsers:** - 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
Means of Collecting Data	Obtained from pre-obtained digital images via PACS system or via Quentry	Obtained from pre-obtained digital images via PACS system
Number of Images that can simultaneously viewed on screen	One	Up to 4
Runs on Server	Yes	Yes
Hip Module	Yes	Yes
Trauma Module	No	Yes
Knee Module	No	Yes
Spinal Module	No	Yes
Pediatric Module	No	Yes
Foot & Ankle Module	No	Yes
Upper Limb Module	No	Yes
Input 3D Images	No	Yes
Digital Prosthetic Templates	Yes	Yes
Interactive template positioning	Yes	Yes

Voyant HEALTH™
a Brainlab Company

Voyant Health Ltd.
35 Efal Street
Petach-Tikva, 4951132
ISRAEL

www.voyanthealth.com

Phone: +972-3-929-0929
Fax: +972-3-923-6413

Parameter/Character	Subject Device TraumaCad Mobile 1.0	Predicate Device TraumaCad 2.0
Automatic Scaling	Yes	Yes
Template support from manufacturers	Yes	Yes
Permits template rotation	Yes	Yes
Pre-operative Planning	Yes	Yes
Patient Contacting	No	No
Control of Life-Saving Devices	No	No
Healthcare professionals intervention for interpretation and manipulation of images	Yes	Yes
510(k) #	K142923 (Pending)	K073714