Brainlab Ltd.
℅ Yael Guttentag
QM & RA Senior Manager
35 Efal Street
Petach-Tikva, 4951132
Israel

November 20, 2023

Re: K231498
Trade/Device Name: TraumaCad Neo
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 18, 2023
Received: October 18, 2023

Dear Yael 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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

Jessica Lamb, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231498

Device Name
TraumaCad Neo

Indications for Use *(Describe)*
TraumaCad Neo is indicated for assisting healthcare professionals to analyze orthopedic conditions and to plan orthopedic procedures by overlaying on relevant radiological images visual information such as measurements and prosthesis templates. Clinical judgment and experience are required to properly use the software. The software is not intended for primary radiological image interpretation or radiological appraisal. Device is not intended 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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BRAINLAB

510(k) Summary

K231498

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

1. (a) Submitter Address:

Brainlab Ltd
35 Efal Street
Petach-Tikva, Israel 4951132

1. (b) *Manufacturer Address:*

Brainlab Ltd
35 Efal Street
Petach-Tikva, Israel 4951132

Mfg. Phone: Tel.: +972-3-929-0929

Contact Person: Mrs. Yael Guttentag

Date: May 22, 2023

2. *Device & Classification Name:*

Radiological Image Processing System –
classified as Class 2 LLZ, Regulation Number 21 CFR 892.2050
TraumaCad Neo

3. *Predicate Device:* TraumaCad Mobile 2.0 (K160001)

4. *Description:*

TraumaCad Neo 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 facilitates the film-less orthopedic practice. TraumaCad Neo also allows post-operative review of images obtained after the surgical procedure. The program features an extensive regularly updated library of digital templates from leading manufacturers. TraumaCad Neo supports DICOM and is integrated to communicate with Quentry®, a proprietary web-based cloud service from Brainlab. It is through Quentry®, where the medical staff can upload images to plan their expected results prior to the procedure to create a smooth surgical workflow from start to finish.

5. *Indications for Use:*

TraumaCad Neo is indicated for assisting healthcare professionals to analyze orthopedic conditions and to plan orthopedic procedures by overlaying on relevant radiological images visual information such as measurements and prosthesis templates. Clinical judgment and experience are required to properly use the software. The software is not intended for primary radiological image interpretation or radiological appraisal. Device is not intended for use on mobile phones.

6. ***Comparison of Technological Characteristics:*** With respect to technology and intended use, TraumaCad Neo is substantially equivalent to its predicate device. Based upon the outcomes from the Risk Analysis and Performance Testing Evaluation, Brainlab Ltd believes that the modification of TraumaCad Mobile 2.0 (predicate device) which allows it to become TraumaCad Neo does not raise additional safety or efficacy concerns. The following comparison table depicts the changes.

Features/ Characteristics	Submitted Device TraumaCad Neo	Predicate Device TraumaCad Mobile Release 2.0
Product Code	LLZ	LLZ
Indication for Use	TraumaCad Neo is indicated for assisting healthcare professionals to analyze orthopedic conditions and to plan orthopedic procedures by overlaying on relevant radiological images visual information such as measurements and prosthesis templates. Clinical judgment and experience are required to properly use the software. The software is not intended for primary radiological image interpretation or radiological appraisal. Device is not intended for use on mobile phones.	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.
Operating System	Microsoft Windows 10 and above iOS 16.x and above MAC OS 11 and above Android 11 and above	MS Windows 7, 8 or 10 iOS 7.x, 8.x or 9.x MAC OS X
Devices Supported	PC MAC iPads Android tablets	PC/MAC iPad 3, 4 and 5 (Air)

Browsers Supported	Microsoft Edge Firefox Chrome Safari (MAC/iOS)	**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
Image Input	Can receive digital images from Quentry®	Can receive digital images from various sources
Means of Collecting Data	Obtained from pre-obtained digital images via Quentry®	Obtained from pre-obtained digital images via PACS or via Quentry®
Number of Images that can simultaneously viewed on the screen	Up to 3	Up to 2
Runs on Server	yes	yes
Hip Module	yes	yes
Knee Module	yes	yes
Foot and Ankle Module	yes	yes
Upper Limb Module	yes	yes
Digital Prosthetic Templates	yes	yes
Interactive template positioning	yes	yes
Automatic Scaling	yes	yes
Template support from manufacturers	yes	yes
Permits Template Rotation	yes	yes
Pre-Operative Planning	yes	yes

Post Operative Review	yes	no
Patient Contacting	no	no
Control of Life Sustaining Devices	no	no
Healthcare professional intervention for interpretation of images	yes	yes
510(k) #	Pending	K160001

7. ***Performance Evaluation:*** The Performance Evaluation of TraumaCad Neo was based upon well-established test methods which demonstrated conformity to the intended use. These test methods were the same which were used to demonstrate the substantial equivalence of the predicate device TraumaCad Mobile 2.0.

8. ***Conclusion:*** The intended use and the fundamental technological characteristics of TraumaCad Neo are the same as those in the TraumaCad Mobile 2.0, which is the predicate device. Any additions or differences do not affect the safety and effectiveness of the device. The performance tests have been completed and successfully confirm the performance of the device. Based upon this data, Brainlab Ltd believes that TraumaCad Neo is substantially equivalent to the predicate device.