June 4, 2025

Brainlab Ltd.
Veronika Kravtsov
RA Manager
35 Efal Street
Petach-Tikva, 4951132
Israel

Re: K243810
Trade/Device Name: TraumaCad Neo (1.1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: May 13, 2025
Received: May 13, 2025

Dear Veronika Kravtsov:

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.

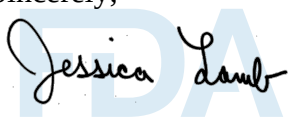
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243810

Device Name

TraumaCad Neo (1.1)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K243810 510(k) Summary

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:*** ***Mfg. Phone:*** ***Contact Person:*** ***Date:***	Brainlab Ltd 35 Efal Street Petach-Tikva, Israel 4951132 Tel.: +972-3-929-0929 Veronika Kravtsov, RA Manager May 8, 2025
2.	***Device & Classification:*** ***Name:***	Radiological Image Processing System – classified as Class 2 QIH and LLZ Regulation Number 21 CFR 892.2050 TraumaCad Neo (1.1)
3.	***Predicate Devices:***	TraumaCad Neo (K231498) PeekMed Web (V1) (K222767)
4.	***Description:***	TraumaCad Neo 1.1 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 a film-less orthopedic practice. TraumaCad Neo 1.1 also allows post-operative review and assessment of X-ray images obtained after the surgical procedure, with a feature for automatic surgery outcome analysis of postoperative total hip arthroplasty images. The program features an extensive regularly updated library of digital templates from leading manufacturers. TraumaCad Neo supports DICOM and is communicating with Quentry®, a proprietary web-based cloud service from Brainlab and with other healthcare data platforms, such as PACS solutions. It is through these healthcare data platforms, 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 1.1 is substantially equivalent to its predicate devices. Based upon the outcomes from the Risk Analysis and Performance Testing Evaluation, Brainlab Ltd. believes that the modification of TraumaCad Neo 1.0 (predicate device) which allows it to become TraumaCad Neo 1.1 does not raise additional safety or efficacy concerns. The following comparison tables depict the changes.

Features/ Characteristics	**Submitted Device: TraumaCad Neo 1.1**	**Predicate Device: TraumaCad Neo 1.0**
Product Code	QIH, 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.	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.

Features/ Characteristics	Submitted Device: TraumaCad Neo 1.1	Predicate Device: TraumaCad Neo 1.0
Operating System	Microsoft Windows 10 and above iOS 17.x and above MAC Sequoia and above Android 14 and above	Microsoft Windows 10 and above iOS 16.x and above MAC OS 11 and above Android 11 and above
Devices Supported	PC MAC iPads Android tablets	PC MAC iPads Android tablets
Browsers Supported	Microsoft Edge Firefox Chrome Safari (MAC/iOS)	Microsoft Edge Firefox Chrome Safari (MAC/iOS)
Image Input	Can receive digital images from PACS solutions, EMR systems, or from Quentry®	Can receive digital images from Quentry®
Number of Images that can simultaneously viewed on the screen	Up to 3	Up to 3
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

Features/ Characteristics	Submitted Device: TraumaCad Neo 1.1	Predicate Device: TraumaCad Neo 1.0
Template support from manufacturers	Yes	Yes
Permits Template Rotation	Yes	Yes
Pre-Operative Planning	Yes	Yes
Post Operative Review	Yes	Yes
Patient Contacting	No	No
Control of Life Sustaining Devices	No	No
Healthcare professional intervention for interpretation of images	Yes	Yes
Software Delivery	Web and locally	Web
Post Operative Landmark Placement	Automatically (AI) for Hip images, manually for other anatomies modules	Manually for all anatomies modules
510(k) #	Pending	K231498

Features/ Characteristics	Submitted Device: TraumaCad Neo 1.1	Predicate Device: PeekMed Web (V1)
Product Code	QIH, LLZ	QIH , 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.	PeekMed web is a system designed to help healthcare professionals carry out pre-operative planning for several surgical procedures, based on their imported patients' imaging studies. Experience in usage and a clinical assessment is necessary for the proper use of the system in the revision and approval of the output of the planning. The multi-platform system works with a database of digital representations related to surgical materials supplied by their manufacturers.
Operating System	Microsoft Windows 10 and above iOS 17.x and above MAC Sequoia and above Android 14 and above	Web base
Devices Supported	PC MAC iPads Android tablets	PC MAC
Image Input	Can receive digital images from PACS solutions, EMR systems, or from Quentry®	Web
Landmarking	Automatic landmarking postoperatively on Hip only. Manual for other anatomy pre and post operatively	Automatic landmarking is a feature designed to accelerate the process of placing the landmarks on each bone before planning the surgery
Anatomic Regions for Templates	Hip, Knee, Upper Limb, Foot and Ankle	Hip, Knee and Upper Limb
Input Images	Xray	CT and Xray
Digital Prosthetic Templates	Yes	Yes
Interactive template	Yes	Yes

Features/ Characteristics	Submitted Device: TraumaCad Neo 1.1	Predicate Device: PeekMed Web (V1)
positioning		
Automatic Scaling	Yes	Yes
Template support from manufacturers	Yes	Yes
Permits Template Rotation	Yes	Yes
Pre-Operative Planning	Yes	Yes
Post Operative Review	Yes	Yes
Patient Contacting	No	No
Control of Life Sustaining Devices	No	No
Healthcare professional intervention for interpretation of images	Yes	Yes
510(k) #	Pending	K222767

7. ***Performance Evaluation:*** The Performance Evaluation of TraumaCad Neo 1.1 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 Neo (K231498).
The AI/ML models incorporated into the TraumaCad Neo 1.1 were trained, tested and validated for their performance, by qualified personnel, based on predefined protocols and criteria.
The automatic postoperative total hip arthroplasty analysis is achieved by the AI/ML based algorithm, by automatically identifying whether a relevant implant is present, and as a next step, if an implant is found, detecting certain landmarks on patient's anatomy and on the implant on the DICOM image.

The AI/ML models were trained with supervision on X-ray image data from multiple clinical sites, including wide variety of scanner models, implants and patient characteristics.

The mentioned AI/ML models are non-adaptive, i.e. do not learn from data once initially trained. The training data was totally separate from the performance testing data. Measures were taken to eliminate bias and prevent overfitting in the data.

The performance testing was based on a data pool containing 349 original X-ray images, which were used in the following way:
For implant detection evaluation, used all 349 images from 186 patients; For landmark detection evaluation, used 184 images from 184 patients.

Each of the selected X-ray images have been augmented 3 times, in order to test the robustness of the detection algorithm to input variations, leading to a sample size of over 1000 images.

The dataset included the following characteristics to ensure generalization:

- All images in this dataset are standing pelvic X-rays
- Pixel spacing is between 0.1 and 0.2 mm both in x and y axes
- Approximately 57% of test set images are from females, while 43% are from male patients
- All patients are adults (≥18 years old) typically in the age range of 30 to 90 and predominantly between the ages 50 and 80, which made up 68% of the entire test set
- Consists of images from seven unique X-ray device manufacturers with 11 unique X-ray device models
- Balanced distribution of implant laterality
- Contains Cup and Stem Implants from multiple manufacturers in a range of sizes
- An independent test dataset (comprising approximately 28% of the test images) from an independent clinical site and X-ray manufacturer was allocated to be able to quantitatively test the algorithm's generalizability to completely unseen data

Accuracy of implant presence and 2D landmark detection have been tested against ground-truth annotations done by qualified and trained personnel. The pre-specified acceptance criteria required that at least 80% of the analyzed femur and implant stem shafts were within 4 mm distance to their ground-truth landmark annotation. The results showed that 99% of the time the machine learning algorithm was able to correctly determine the implant presence and 92% of the landmarks were successfully detected automatically within 4mm distance from their corresponding ground-truth landmark annotations. Therefore, tests showed that the AI/ML model yields acceptable performance for the intended use.

8. ***Conclusion:*** The intended use and the fundamental technological characteristics of TraumaCad Neo 1.1 are the same as those in the TraumaCad Neo (1.0), 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 1.1 is substantially equivalent to the predicate devices.