Peek Health, S.A.
Sara Silva
Chief Quality Officer (CQO)
Centro de Negócios Ideia Atlântico, Rua Padres Carmelitas
Braga, 4719-005
Portugal

Re: K240926 December 6, 2024
Trade/Device Name: PeekMed web
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, QIH
Dated: November 1, 2024
Received: November 1, 2024

Dear Sara Silva:

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.

510(k) Number *(if known)*
K240926

Device Name
PeekMed web

Indications for Use *(Describe)*
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.

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.

510(k) summary / K240926

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

Peek Health, S.A.
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Portugal

Contact Person:	Sara Silva Chief Quality Officer (CQO) Email: sara.silva@peekmed.com Office number: + 351 253 128 941
Date Summary Prepared:	December 5, 2024

2. Device

2.1 PeekMed web

Trade Name:	PeekMed web
Common or Usual Name:	Medical image management and processing system
Classification Name:	System, Image Processing, Radiological (21 C.F.R. § 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ/QIH

3. Legally Marketed Predicate Device

3.1 PeekMed web

510(k)	Product Name	Clearance Date
K222767	PeekMed web	December 2022

4. Device Description Summary

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.

As PeekMed web is capable of representing medical images in a 2D or 3D environment, performing relevant measurements on those images, and also capable of adding templates, it then can perform a total overview of the surgery. Being software it does not interact with any part of the body of the user and/or patient.

5. Intended Use/Indications for Use

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.

5.1. Contraindications

No contraindications specific to this device.

5.2 Indications for Use Comparison

There are NO differences between the indications for use of this device and its predicate.

6. Technological Comparison to Predicate

PeekMed web was compared to its respective predicate device in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent. Any

technological differences within this 510(k), between the subject device and the predicate device, do not impact substantial equivalence, or safety and effectiveness.

The subject device and its predicate are both medical software that allows healthcare professionals to perform orthopedic pre-surgical planning efficiently in the musculoskeletal system of adults in a healthcare environment, therefore sharing the same intended use, intended user, and intended patient population. To properly and fully use both devices, clinical judgment, and experience are mandatory.

Both devices have the same workflows, use requirements (e.g., internet connection, output validation), and planning features (e.g., model representation, digital overlap of prosthetic material, possible 2D and 3D environments). Both devices generate a final report of the planning which consists of the selected images with templates, measurements, and textual information describing the patient and/or the surgical procedure to be performed.

Table 1: Summary of Predicate and Subject Device Characteristics to Demonstrate Substantial Equivalence

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
Product Code	LLZ, QIH	LLZ, QIH	**Yes**	---
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	**Yes**	---
Regulation Name	Medical Image Management And Processing System	Medical Image Management And Processing System	**Yes**	---
Intended use	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.	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.	**Yes**	---
Indications for	This medical device consists of a	This medical device consists of a	**Yes**	---

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
use	decision support tool for qualified healthcare professionals to quickly and efficiently perform the pre-operative planning for several surgical procedures, using medical imaging with the additional capability of planning the 2D or 3D environment. The system is designed for the medical specialties within surgery and no specific use environment is mandatory, whereas the typical use environment is a room with a computer. The patient target group is adult patients who have an injury or disability diagnosed previously. There are no other considerations for the intended patient population.	decision support tool for qualified healthcare professionals to quickly and efficiently perform the pre-operative planning for several surgical procedures, using medical imaging with the additional capability of planning the 2D or 3D environment. The system is designed for the medical specialties within surgery and no specific use environment is mandatory, whereas the typical use environment is a room with a computer. The patient target group is adult patients who have an injury or disability diagnosed previously. There are no other considerations for the intended patient population.		
Contraindications	No contraindications specific to this device.	No contraindications specific to this device.	**Yes**	---
Clinical purpose	PeekMed web allows the surgeon to perform orthopedic pre-surgical planning efficiently in the	PeekMed web allows the surgeon to perform orthopedic pre-surgical planning efficiently in the	**Yes**	---

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
	musculoskeletal system (e.g., Hip procedures, Knee procedures)	musculoskeletal system (e.g., Hip procedures, Knee procedures)		
Anatomical regions	PeekMed web allows the surgeon to perform the pre-surgical planning efficiently in the following anatomical regions: - Hip - Knee - Upper limb	PeekMed web allows the surgeon to perform the pre-surgical planning efficiently in the following anatomical regions: - Hip - Knee - Upper limb - Foot	**Yes** The subject device also allows the planning of orthopedic surgery in the foot region.	The subject device allows for the surgery planning on one more anatomical region (**foot**), this does not constitute a new intended purpose nor does it raise questions of safety and performance, since the development, verification, validation, and release processes are exactly the same between the devices. The new variants of the ML model for foot are considered in this Traditional 510(k) and were developed according to what is defined for each ML model development and validation according to their intended requirements and performance. This change improves the medical device in a way that the user can benefit from the existing features on one more anatomical region. This change does not interfere with or create an effect on other anatomical regions covered by the device.
Patient Population	Adults	Adults	**Yes**	---

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
End users	Healthcare Professionals	Healthcare Professionals	**Yes**	---
Device availability	Software is cloud-based (not installable) and can be displayed on any personal device or workstation that can run on a web browser	Software is cloud-based (not installable) and can be displayed on any personal device or workstation that can run on a web browser	**Yes**	---
Software Architecture	Distributed system (cloud-based). This distributed system is a combination of software modules placed on servers that are able to communicate with each other.	Distributed system (cloud-based). This distributed system is a combination of software modules placed on servers that are able to communicate with each other.	**Yes**	---
Workflow	The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case. The workflow chart is in Annex 2.	The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case. The workflow chart is in Annex 2.	**Yes**	---
Internet connection	Required	Required	**Yes**	---
Images source	Receives medical images from various sources	Receives medical images from various sources	**Yes**	---
Data processing	The software processes data to provide an overlap and	The software processes data to provide an overlap and	**Yes**	---

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
	dimensioning of digital representations of the prosthetic material	dimensioning of digital representations of the prosthetic material		
Digital overlap of templates	Allows the overlap of models and the intersection of the models	Allows the overlap of models and the intersection of the models	**Yes**	---
Interactive model positioning	Yes	Yes	**Yes**	---
Interactive model dimensioning	Yes	Yes	**Yes**	---
Model rotation	Yes	Yes	**Yes**	---
Support for digital prosthetic materials provided by the manufacturers	Yes	Yes	**Yes**	---
Pre-surgical planning	Yes	Yes	**Yes**	---
Type of pre-surgical planning	Automatic or Manual	Automatic or Manual	**Yes**	---
Contact with the patient	No	No	**Yes**	---

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
Control of life supporting devices	No	No	**Yes**	---
Human intervention for image interpretation	Yes	Yes	**Yes**	---
Ability to add additional modules when available	Yes	Yes	**Yes**	---
Automatic bone segmentation	Yes	Yes	**Yes** The updated ML model variants were compared against the acceptance criteria and, therefore confirmed to be an improvement	The subject device includes new and updated ML model variants for the purpose of bone segmentation. These ML model variants were developed and validated using the same methods and acceptance criteria and deemed as Compliant. The updated model variants were also compared against the acceptance criteria, therefore confirmed to be an improvement over the last ML model variants versions.

Characteristic	PeekMed web Predicate device K222767	PeekMed web Subject device	Substantially Equivalent?	Justification and rationale
			over the last ML model variants versions.	
Configuration Windows for Oblique Planes functionality	Yes	Yes		---
Type of landmarking	Automatic or Manual	Automatic or Manual	**Yes** The updated ML model variants were compared against the acceptance criteria and, therefore confirmed to be an improvement over the last ML model variants versions.	The subject device includes new and updated ML model variants for the purpose of landmarking. These ML model variants were developed and validated using the same methods and acceptance criteria and deemed as Compliant. The updated model variants were also compared against the acceptance criteria, therefore confirmed to be an improvement over the last ML model variants versions.

PeekMed web shares the same intended use, indications for use, end users, and has patient population, and overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device. The subject device has the same design and function as the predicate device for the modes of operation and use. The subject device includes new/improved ML models and variants.

7. Performance Data

Nonclinical performance testing performed on the subject device, PeekMed web, supports substantial equivalence to the predicate device. The following testing was performed on the subject device:

A. Verification activities to ensure that features were implemented following the requirements and covering the acceptance criteria.
B. ML models incorporated into PeekMed web were also developed, trained, tested, and externally validated for their performance according to the internal procedures.
    - A dedicated validation dataset containing different data from the ML development dataset was used. Specifically, the validation dataset was not a sampling of the development dataset, has never been used for the algorithm training or for tunning the algorithm, and leakage between development and validation data sets did not occur.

Training, development, testing and external validation data information

ML models were developed with datasets from multiple sites in a total of 2852 CR datasets, and 1903 CT scans. We trained the ML models with 80% of the datasets, developed with 10%, and tested with the remaining 10%. External validation is performed by sample size with a total unique dataset, for segmentation ML model: 367; Landmarking ML model: 367; and Classification ML model: 367. This comprehensive dataset was designed to cover the intended use population while ensuring a variety of data maintaining diverse patient characteristics.

Subgroup definition (generalizability)

Datasets were divided according to the subgroups listed below:

- Demographics
    - Patient Sex
    - Patient Age
- Equipment and Protocols for Image Collection
    - Institution Name
    - Manufacturer
    - Manufacturer Model Name

Acceptance criteria

The acceptance criteria for each ML model are shown in the following table:

ML model	Acceptance Criteria
Segmentation	DICE is no less than 90% HD-95 is no more than 8 STD DICE is between +/- 10% Precision is more than 85% Recall is more than 90%
Landmarking	MRE is no more than 7mm STD MRE is between +/- 5mm
Classification	Accuracy is no less than 90%. Precision is no less than 85% Recall is no less than 90% F1 score is no less than 90%

Reference Standard ("Truthing" Process)

Comparison of the efficacy results of the Bone Segmentation ML model using the testing and external validation datasets against the predefined ground truth met the acceptance criteria for ML model performance, demonstrating the substantial equivalence of the subject device to its predicate.

Comparison of the efficacy results of the Landmarking ML model using the testing and external validation datasets against the predefined ground truth met the acceptance criteria for ML model performance, demonstrating the substantial equivalence of the subject device to its predicate.

Comparison of the efficacy results of the Classification ML model using the testing and external validation datasets against the predefined ground truth met the acceptance criteria for ML model performance, demonstrating the substantial equivalence of the subject device to its predicate.

Independence of Training and External Validation Data

External validation datasets were collected independently of the development data to prevent bias, ensuring the reliability of the results. For the external validation, a fully independent dataset, labeled by a separate team, was employed to provide an accurate assessment of the model's performance, over the whole population and for each sub-group mentioned before in order to prove that it generalizes well to unseen, real-world data. All the testing and external validation performed indicate acceptable performances of the ML models for its intended population.

C. Validation tests were performed internally before the release to the market by qualified personnel, in an environment simulating the real end-user environment. This validation follows a pre-defined test script document, according to the tests defined in the TestRail.

Nonclinical performance testing allowed us to understand that there are no related problems in the subject device. Furthermore, these tests will be repeated and updated when appropriate to ensure that the software is always properly validated, making it possible to understand in which version the problems arise and in which they are solved. Consequently, any problem that may appear in a given PeekMed web version will be identified and can be solved in subsequent versions, as all steps are traceable. All anatomical areas were tested, as well as other main areas of the software, such as the planning final report, and saved planning, ML models, among others.

After these successful validation tests, it is possible to deem the subject device, PeekMed web, as substantially equivalent to its predicate device.

9. Conclusion

Based on the information provided in this 510(k) submission, it was determined that the subject device, PeekMed web, is substantially equivalent to the legally marketed predicate device concerning indications for use, intended use, design, technology, and performance.