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

December 30, 2022

Re: K222767
Trade/Device Name: PeekMed web (v1)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: November 28, 2022
Received: November 30, 2022

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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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.

Submission Number *(if known)*

K222767

Device Name

PeekMed web (v1)

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.

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510(k) Summary

510(k) #: K222767

Prepared on 2022-12-30

1. Contact Details

Applicant Name: Peek Health, S.A.

Applicant Address: Centro de Negócios Ideia Atlântico, Rua Padres Carmelitas Braga - 4719-005 Portugal

Applicant Contact Telephone: +351935147151

Applicant Contact: Ms. Sara Silva

Applicant Contact Email: sara.silva@peekmed.com

2. Device Name

Device Trade Name: PeekMed web (v1)

Common Name: Medical image management and processing system

Classification Name: System, Image Processing, Radiological

Regulation Number: 892.2050

Product Code: QIH/LLZ

3. Legally Marketed Predicate Devices

Predicate #: K182464

Predicate Trade Name: PeekMed

Product Code: LLZ

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 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 the 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.

6. Indications for Use Comparison

The differences between the indications for use of PeekMed and PeekMed web are:

- PeekMed supports importing medical images from PACS while PeekMed web does not.
- PeekMed supports the use of MRI medical images while PeekMed web does not.

The differences specified above do not constitute a new intended purpose because they only regard clinically irrelevant features, the image import feature. The intended purpose of both the device and its predicate is to serve as a support tool for orthopedic surgery planning. It can be concluded that the differences do not raise new questions of safety and effectiveness of the device compared to the predicate.

7. Technological Comparison

The device and its predicate are both medical softwares that allow healthcare professionals to perform orthopedic pre-surgical planning efficiently in the musculoskeletal system (e.g., Hip procedures, Knee procedures) of adults in an healthcare environment, therefore share the same

intended use, similar intended user a similar intended population. To properly use both devices, clinical judgment and experience is mandatory.

Both devices have similar workflows, use requirements (e.g., internet connection, output validation), 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, textual information describing the patient and/or the surgical procedure to be performed. The final report may be previewed, saved and printed.

However, the device and its predicate have the following differences:

1. PeekMed is an installable software system that runs on a personal computer or workstation while PeekMed web is a cloud-based software system that runs on servers and can be displayed on a web browser.

2. The architecture design chart is different when comparing to the predicate device.

3. PeekMed only supports manual planning while PeekMed web also supports automatic planning. Automatic planning is required to be validated by the qualified medical specialist (user) and can be manually changed depending on the preferences

4. PeekMed only supports manual placement of the landmarks on each bone by the medical specialist, while PeekMed web supports automatic positioning of the landmarks which are then required to be validated by the medical specialist (user) and can be manually placed when appropriate.

5. PeekMed® allows the surgeon to perform the pre-surgical planning efficiently in the following anatomical regions: Hip, Knee, Spine, Upper limb, Foot and Ankle while PeekMed® web only allows Hip, Knee, Upper limb.

6. The predicate device's patient population are both adults and pediatrics, while PeekMed web patient population is only adults.

7. PeekMed® end users are Surgerons while in PeekMed® web are Healthcare Professionals.

These differences do not raise any the safety or effectiveness questions when compared to the predicate because:

1. Although the device availability is different when compared to the predicate device, it is broader and wider in PeekMed® web, therefore providing more device options for use. Also,

PeekMed® web is verified and validated to run on servers and to be displayed on a web browser. The device where the user interacts with the medical device is not clinically relevant and does not affect the clinical output, therefore does not raise any safety or effectiveness questions when compared to the predicate nor does it change the intended use of the device.

2. Although the software architecture is different, because the predicate is a desktop installable and PeekMed® web is a cloud-based system, both softwares workflows are similar and have the same clinically relevant base functions. Also, PeekMed® web's distributed system normal functioning is verified and validated as a whole. The architecture difference is not clinically relevant, therefore does not raise any safety or effectiveness questions when compared to the predicate nor does it change the intended use of the device.

3. Automatic planning supported by PeekMed® web is a feature designed to improve and accelerate the user planning experience and is not to be considered medical advice. An automatic plan is always reviewed and validated by the qualified medical specialist and, when needed, it can be manually changed, being the clinical outputs the same as the predicate. Also, PeekMed® web was tested and validated regarding the automatic planning feature performance. For all the reasons above, it can be concluded that the automatic planning does not introduce new severe risks to the process, does not raise any safety or effectiveness questions when compared to the predicate and does not change the intended use of the device.

4. Automatic landmarking is a feature designed to accelerate the process of placing the landmarks on each bone before planning the surgery and its purpose is not to give medical advice on where the landmarks should be positioned. It is mandatory that the qualified user validates each individually landmark automatically positioned while it is possible to manually change them when needed. Also, PeekMed® web was tested and validated regarding automatic landmarking performance. For all the reasons above, it can be concluded that the automatic landmarking does not introduce new severe risks to the process, does not raise any safety or effectiveness questions when compared to the predicate and does not change the intended use of the device.

5. All anatomical regions covered in PeekMed web are included in its predicate (hip, knee, and upper limb). Although the predicate device includes two more anatomical regions than PeekMed web, this does not constitute a new intended purpose nor does raise questions of safety and effectiveness when compared to the predicate, since the existence of two more regions does not interfere or create an effect on other anatomical regions covered by the device.

6. Although the patient population is not the same, it is broader in the predicate device as it also includes pediatric additionally to Adults. This difference is mainly due to PeekMed web incorporating 2 ML models (for bone segmentation and landmarking) while its predicate device does not include any. For the development of these 2 ML models, it was verified that no pediatric images were used. Also the following problems were considered: There is a huge variability on the human body musculoskeletal structure while its in development; The ratio of

orthopedics pediatric medical images available on the market, when compared to Adults medical images is low; It was concluded that using pediatric datasets to develop ML models would only introduce noise and would not be beneficial. For the reasons stated , it can be concluded that this difference does not raise any safety or effectiveness questions when compared to the predicate nor does constitute a new intended purpose.

7. Both softwares intended purpose is the same, pre-operative planning softwares for surgery. To address the problem that that more users need to consult the software (such as: nurses who need to consult the planning or the medical images to provide better medical assistant; other qualified medical professionals, that are not surgeons, that need to consult the planning or the medical images to provide valuable feedback), PeekMed web end users were extended to Healthcare Professionals and not only the Surgeons. However, as PeekMed web documentation refers, only qualified users (trained surgeons) can perform activities related to the approval of clinical and critical information to achieve the clinical output of the software (such as landmarking approval). This difference is an improvement of the description of the software and does not raise any safety or effectiveness question when compared to the predicate, nor does it change the software indications for use when compared to its predicate.

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

Nonclinical tests submitted consist of:

- Validation tests performed internally prior to 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.
- ML models incorporated into PeekMed web were also trained, tested and validated for their performance.
- To reassure that the lengths and angles measured with the measuring function of PeekMed® web software effectively and repeatedly match the real dimensions. Validation phase ensures that all product requirements have been fulfilled, meets the end-users needs, and ensures the safety and proper performance of the device compared to the predicate.

Nonclinical tests allowed to understand that there is no related problems in this device. Furthermore, these tests will be repeated and updated when appropriate in order to ensure that the software is always properly validated, being 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. The measuring function of the software was verified and validated, in order to assure the safety and correct performance of the device compared to the predicate. It was confirmed that it fulfills the previously defined accuracy and precision specifications.

After these successful validation tests, it is possible to deem PeekMed® web v1.0.0.0 as substantially equivalent to its predicate device.