



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

March 19, 2025

Re: K250042

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: QIH, LLZ  
Dated: January 8, 2025  
Received: January 8, 2025

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

## Indications for Use

Submission Number (if known)

K250042

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.

This medical device consists of a 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.

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

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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Rua Padres Carmelitas  
4719-005 Braga  
Portugal

Contact Person: Sara Silva  
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Office number: + 351 253 128 941

Date Summary Prepared: March 17, 2025

### 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: QIH, LLZ

### 3. Legally Marketed Predicate Device

#### 3.1 PeekMed web

| 510(k)  | Product Name | Clearance Date   |
|---------|--------------|------------------|
| K240926 | PeekMed web  | December 6, 2024 |



#### **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.

This medical device consists of a 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.

##### **5.1. Contraindications**

No contraindications specific to this device.



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## 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<br>Predicate device K240926                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | PeekMed web<br>Subject device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Substantially<br>Equivalent? | Justification and rationale |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <b>Product Code</b>                     | QIH, LLZ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | LLZ, QIH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Yes</b>                   | ---                         |
| <b>Regulation Number</b>                | 21 CFR 892.2050                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 21 CFR 892.2050                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Yes</b>                   | ---                         |
| <b>Regulation Name</b>                  | Medical Image Management And Processing System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Medical Image Management And Processing System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Yes</b>                   | ---                         |
| <b>Intended use/Indications for use</b> | <p>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.</p> <p>This medical device consists of a 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</p> | <p>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.</p> <p>This medical device consists of a 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</p> | <b>Yes</b>                   | ---                         |

| Characteristic            | PeekMed web<br>Predicate device K240926                                                                                                                                                                                                                                                                                                                                                                  | PeekMed web<br>Subject device                                                                                                                                                                                                                                                                                                                                                              | Substantially<br>Equivalent? | Justification and rationale |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
|                           | 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. | 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. |                              |                             |
| <b>Contraindications</b>  | No contraindications specific to this device.                                                                                                                                                                                                                                                                                                                                                            | No contraindications specific to this device.                                                                                                                                                                                                                                                                                                                                              | <b>Yes</b>                   | ---                         |
| <b>Clinical purpose</b>   | PeekMed web allows the surgeon to perform orthopedic pre-surgical planning efficiently in the musculoskeletal system (e.g., Hip procedures, Knee procedures)                                                                                                                                                                                                                                             | PeekMed web allows the surgeon to perform orthopedic pre-surgical planning efficiently in the musculoskeletal system (e.g., Hip procedures, Knee procedures)                                                                                                                                                                                                                               | <b>Yes</b>                   | ---                         |
| <b>Anatomical regions</b> | PeekMed web allows the surgeon to perform the pre-surgical planning efficiently in the following anatomical regions:<br>- Hip<br>- Knee<br>- Upper limb<br>- Foot                                                                                                                                                                                                                                        | PeekMed web allows the surgeon to perform the pre-surgical planning efficiently in the following anatomical regions:<br>- Hip<br>- Knee<br>- Upper limb<br>- Foot                                                                                                                                                                                                                          | <b>Yes</b>                   | —                           |
| <b>Patient Population</b> | Adults                                                                                                                                                                                                                                                                                                                                                                                                   | Adults                                                                                                                                                                                                                                                                                                                                                                                     | <b>Yes</b>                   | ---                         |

| Characteristic                       | PeekMed web<br>Predicate device K240926                                                                                                                        | PeekMed web<br>Subject device                                                                                                                                  | Substantially<br>Equivalent? | Justification and rationale |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <b>End users</b>                     | Healthcare Professionals                                                                                                                                       | Healthcare Professionals                                                                                                                                       | <b>Yes</b>                   | ---                         |
| <b>Device availability</b>           | 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                             | <b>Yes</b>                   | ---                         |
| <b>Software Architecture</b>         | 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. | <b>Yes</b>                   | ---                         |
| <b>Workflow</b>                      | The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case.                               | The workflow is as follows: Import case images, configure images, identify the case, pre-surgical planning, and export the case.                               | <b>Yes</b>                   | ---                         |
| <b>Internet connection</b>           | Required                                                                                                                                                       | Required                                                                                                                                                       | <b>Yes</b>                   | ---                         |
| <b>Images source</b>                 | Receives medical images from various sources                                                                                                                   | Receives medical images from various sources                                                                                                                   | <b>Yes</b>                   | ---                         |
| <b>Data processing</b>               | The software processes data to provide an overlap and dimensioning of digital representations of the prosthetic material                                       | The software processes data to provide an overlap and dimensioning of digital representations of the prosthetic material                                       | <b>Yes</b>                   | ---                         |
| <b>Digital overlap of templates</b>  | Allows the overlap of models and the intersection of the models                                                                                                | Allows the overlap of models and the intersection of the models                                                                                                | <b>Yes</b>                   | ---                         |
| <b>Interactive model positioning</b> | Yes                                                                                                                                                            | Yes                                                                                                                                                            | <b>Yes</b>                   | ---                         |
| <b>Interactive model</b>             | Yes                                                                                                                                                            | Yes                                                                                                                                                            | <b>Yes</b>                   | ---                         |

| Characteristic                                                                | PeekMed web<br>Predicate device K240926 | PeekMed web<br>Subject device | Substantially<br>Equivalent? | Justification and rationale        |
|-------------------------------------------------------------------------------|-----------------------------------------|-------------------------------|------------------------------|------------------------------------|
| <b>dimensioning</b>                                                           |                                         |                               |                              |                                    |
| <b>Model rotation</b>                                                         | Yes                                     | Yes                           | <b>Yes</b>                   | ---                                |
| <b>Support for digital prosthetic materials provided by the manufacturers</b> | Yes                                     | Yes                           | <b>Yes</b>                   | ---                                |
| <b>Pre-surgical planning</b>                                                  | Yes                                     | Yes                           | <b>Yes</b>                   | ---                                |
| <b>Type of pre-surgical planning</b>                                          | Automatic or Manual                     | Automatic or Manual           | <b>Yes</b>                   | ---                                |
| <b>Contact with the patient</b>                                               | No                                      | No                            | <b>Yes</b>                   | ---                                |
| <b>Control of life supporting devices</b>                                     | No                                      | No                            | <b>Yes</b>                   | ---                                |
| <b>Human intervention for image interpretation</b>                            | Yes                                     | Yes                           | <b>Yes</b>                   | ---                                |
| <b>Ability to add additional modules when available</b>                       | Yes                                     | Yes                           | <b>Yes</b>                   | ---                                |
| <b>Automatic bone</b>                                                         | Yes                                     | Yes                           | <b>Yes</b>                   | The subject device includes new ML |

| Characteristic                 | PeekMed web<br>Predicate device K240926                                                                                                                                                              | PeekMed web<br>Subject device                                                                                                                                                                                         | Substantially<br>Equivalent? | Justification and rationale                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>segmentation</b>            | <ul style="list-style-type: none"> <li>- Hip (X-ray and CT scan)</li> <li>- Knee (X-ray and CT scan)</li> <li>- Upper limb (CT scan)</li> <li>- Foot (CT scan)</li> </ul>                            | <ul style="list-style-type: none"> <li>- Hip (X-ray and CT scan)</li> <li>- Knee (X-ray and CT scan)</li> <li>- Upper limb (CT scan)</li> <li>- Foot (<u>X-ray</u> and CT scan)</li> </ul>                            |                              | <p>model variants for segmentation. Both devices allow the planning for foot region with CT scans but the subject device also allows with X-ray images.</p> <p>This does not constitute an intended purpose update nor does it raise questions of safety and performance, since the development, verification, validation, and deployment processes are the same for both devices.</p>                                   |
| <b>Type of<br/>landmarking</b> | <p>Automatic or Manual</p> <ul style="list-style-type: none"> <li>- Hip (X-ray and CT scan)</li> <li>- Knee (X-ray and CT scan)</li> <li>- Upper limb (CT scan)</li> <li>- Foot (CT scan)</li> </ul> | <p>Automatic or Manual</p> <ul style="list-style-type: none"> <li>- Hip (X-ray and CT scan)</li> <li>- Knee (X-ray and CT scan)</li> <li>- Upper limb (CT scan)</li> <li>- Foot (<u>X-ray</u> and CT scan)</li> </ul> | <b>Yes</b>                   | <p>The subject device includes new ML model variants for landmarking. Both devices allow the planning for foot region with CT scans but the subject device also allows with X-ray images.</p> <p>This does not constitute an intended purpose update nor does it raise questions of safety and performance, since the development, verification, validation, and deployment processes are the same for both devices.</p> |

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



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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 the 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 tuning 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: 375; Landmarking ML model: 345; Classification ML model: 347; and Detection ML model: 198. 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                                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Segmentation</b>   | DICE is no less than 90%<br>HD-95 is no more than 8<br>STD DICE is between +/- 10%<br>Precision is more than 85%<br>Recall is more than 90% |
| <b>Landmarking</b>    | MRE is no more than 7mm<br>STD MRE is between +/- 5mm                                                                                       |
| <b>Classification</b> | Accuracy is no less than 90%.<br>Precision is no less than 85%<br>Recall is no less than 90%<br>F1 score is no less than 90%                |
| <b>Detection</b>      | MAP is no less than 90%.<br>Precision is no less than 85%<br>Recall is no less than 90%                                                     |

### Reference Standard (“Truthing” Process)

Comparison of the efficacy results of the 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.

Comparison of the efficacy results of the Detection 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 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.



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## 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.