Peek Health, S.A.
% Rachel Paul
Senior Consultant, QA&RA
Emergo Europe Consulting
Prinsessegracht 20
THE HAGUE, 2514 AP NETHERLANDS

October 25, 2018

Re: K182464
Trade/Device Name: PeekMed
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 6, 2018
Received: September 10, 2018

Dear Rachel Paul:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.25 13:24:17 -04'00'

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182464

Device Name
PeekMed

Indications for Use *(Describe)*
PeekMed is a software system designed to help surgeons' specialists carry out the pre-operative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies.
The software imports diagnostics imaging studies such as x-rays, CT or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies.
PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.

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

DEVICE NAME

K 182464

1. Submission Sponsor

Peek Health, S.A.

Praça Conde de Agrolongo, nº123

4700-312

Braga

Portugal

Sara Silva

Chief Quality Officer (CQO)

2. Submission Correspondent

Emergo Europe Consulting

Prinsessegracht 20

The Hague

2514 AP

The Netherlands

Rachel Paul

Senior Consultant, QA & RA

Email: LST.AUS.Projectmanagement@ul.com

3. Date Prepared

September 6, 2018

4. Device Identification

Trade/Proprietary Name: PeekMed

Common/Usual Name: Pre-operative planning software

Classification Name: Picture Archiving and Communications System (PACS)

Regulation Number: 892.2050

Product Code: LLZ, System, Image Processing, Radiological

Device Class: Class II

Classification Panel: Radiology

5. Legally Marketed Predicate Device(s)

510(K) No.	K073714
Clearance date	03/19/2008
Device Name	TraumaCad version 2.0
Manufacturer	Orthocrat, Ltd

6. Indications for Use Statement

PeekMed is a software system designed to help surgeons' specialists carry out the pre-operative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies.

The software imports diagnostics imaging studies such as x-rays, CT or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies.

PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.

7. Device Description

PeekMed is a standalone software application that helps specialist doctors and surgeons to perform the pre-surgical planning for different procedures in a fast and effective way, based on the imaging studies of the patients.

PeekMed is a 3D pre-operative planning software for surgery. This software system allows surgeons to plan a surgery procedure simulating various environments, from hybrid (2D/3D) to 3D or 2D environments.

The software imports diagnostic imaging studies such as X-rays, Computed Tomography (CT) or Magnetic Resonance Image (MRI). The import process can retrieve files from a CD Rom, a local folder or the Picture Archiving and Communications System (PACS) of the hospital/health center. In parallel, there is a database containing digital representations related to prosthetic materials supplied by their respective manufacturers. This offers the possibility of inserting templates of the materials to be used in the surgery in addition to the measurements, making a complete overview of the surgery.

In the case of a 3D or hybrid environment, the surgeon can resort to 3D model generated from a previous imaging study on the patient and 3D digital representations of the prosthetic material to be used during surgery, i.e. screws, fixation plates or full prosthesis, deriving from several producing companies.

8. Substantial Equivalence Discussion

The following table compares PeekMed to the predicate device with respect to indications for use, principles of operation, technological characteristics, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**510(K) Submitter**	**Predicate**	**Significant Differences**
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
510(k) Number	N/A	K140434	N/A
Product Code	LLZ	LLZ	N/A
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	N/A
Regulation Name	System, Image Processing, Radiological	System, Image Processing, Radiological	N/A
Intended for use	PeekMed is a pre-operative planning software for surgery.	TraumaCad is a pre-operative planning software for surgery.	N/A
Indications for use	PeekMed is a software system designed to help surgeons' specialists carry out the pre-operative planning in a prompt and efficient manner for several surgical procedures, based on their patients' imaging studies. The software imports diagnostics imaging studies such as x-rays, CT	The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images and includes tools for performing measurements on the image and for positioning the template. Clinical	In more to 2D, PeekMed can offer a 3D pre-surgical planning or a hybrid 2D/3D environment in addition to isolated 2D and 3D. PeekMed has been tested and validated for 3D and hybrid planning.

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
	or magnetic resonance image (MRI). The import process can retrieve files from a CD ROM, a local folder or the PACS. In parallel, there is a database of digital representations related to prosthetic materials supplied by their producing companies. PeekMed allows health professional to digitally perform the surgical planning without adding any additional steps to that process. This software system requires no imaging study acquisition specification (no protocol). Experience in usage and a clinical assessment are necessary for a proper use of the software.	judgments and experience are required to properly use the software.	
Subspecialties	PeekMed allows the surgeon to perform the pre-surgical planning efficiently in the following subspecialties: - Hip - Knee - Spine - Upper Limb - Foot and Ankle	TraumaCad provides easy-to-use solutions for various orthopedic subspecialties: - Hip - Knee - Pediatric - Trauma - Deformity Analysis	Orthopedic subspecialties supported by PeekMed are also covered in TraumaCad. The majorities of the procedures supported by PeekMed are also supported by TraumaCad. The procedures that are not common to both devices have been tested

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
	- Trauma For each subspecialty, there are several procedures: -Hip: Hip Dysplasia Correction, Limb Length Discrepancy, Center of Rotation – Ranawat method, Acetabular Angle, Total Hip Arthroplasty -Knee: Leg Deformity Correction, AP Knee Resection, AP Full Leg resection, High Tibial Osteotomy, ACL Tunnel Reconstruction, Medial Patellofemoral Ligament -Spine: Single Cobb Angle, Thoracic Kyphosis Angle, Lumbar Lordosis Angle, Sagittal Vertical Axis, Pelvic Angles, Coronal Balance, Sacro-femoral Angle, Sagittal Balance, Smith-Petersen Osteotomy, Pedicle Subtraction Osteotomy	- Spine - Foot and Ankle - Upper Limb The following measurements can be made using TraumaCad measurements tools: -Hip: Hip Deformity Analysis, Polyethylene Wear Wizard, Leg Length Discrepancy Tool, Acetabular Index, VCA Angle of Lequesne, Cup Version, Center of Rotation, Stem Version -Knee: Limb Alignment Analysis, Center Line Finder, Simple Line, High Tibial Osteotomy, Tibial Cutting, Joint Line -Spine: Vertebrae Labeling, Cobb Angle, Double Cobb Angle, Triple Cobb Angle, Pelvic Radius Angle, Sacral Obliquity, , Coronal Balance, Sagittal Balance, Spondylolysthesis, Thoracic Kyphosis Angle, Thoracic Trunk Shift, T1 Tilt Angle, Lumbar Lordosis, Spine Slip Angle	and validated through PeekMed development. It does not raise different questions of safety or effectiveness.

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
	-Upper Limb: Total Shoulder Replacement, Clavicular Angle, Shoulder Resurfacing -Foot and Ankle: Talar Tilt, Hallux Valgus, Moreau-Costa-Bertani Internal Angle, Moreau-Costa-Bertani External Angle, Maestro Formula -Trauma: Diaphyseal Shaft Fracture Angle, Metaphyseal Shaft Fracture Angle, Roof Arc	Upper Limb: Center Line Finder, Simple Line, Joint Line -Foot and ankle: Foot Osteotomies Wizard, Hallux Valgus Angle, Hallux Valgus Interphalangeus Angle, Intermetatarsal Angle, Distal Metatarsal Articular Angle (DMAA), Proximal Metatarsal Articular Angle (PMAA), Talar Tilt -Trauma: Limb Alignment Analysis, Diaphyseal Fracture Angulation, Metaphyseal Fracture Angulation, Center Line Finder, Simple Line, Roof Arc, Joint Line -Pediatric: Hip Deformity Analysis, Limb Alignment Analysis, Acetabular Index, Reimer's Index, VCA Angle of Lequesne	
Patient Population	Adults and pediatrics	Adults and pediatrics	N/A
End users	Surgeons	Surgeons	N/A
Computer	Personal Computer or Workstation	Personal Computer or Workstation	N/A

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
Operating System	Windows or OS X	Windows	PeekMed can run through Windows or OSX and has been tested and validated for the both systems.
Device availability	It can be set to start from a workstation or standalone for planning procedures	It can be set to start from a workstation or standalone for planning procedures	N/A
Images source	Receives medical images from various sources (including PACS)	Receives medical images from various sources (including PACS)	N/A
Data processing	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material	N/A

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	Orthocrat, Ltd	
Device Trade Name	PeekMed	TraumaCad version 2.0	
Digital overlap of prosthetic material	Allows the overlap of models and the intersection of the models	Allows the overlap of models	The additional feature from PeekMed of allowing the intersection of the models has been tested and validated and does not raise different questions of safety or effectiveness.
Interactive model positioning	Yes	Yes	N/A
Interactive model dimensioning	Yes	Yes	N/A
Model rotation	Yes	Yes	N/A
Support for digital prosthetic materials provided by the manufacturers	Yes	Yes	N/A
Automatic calibration	Yes	Yes	N/A
Pre-surgical planning	Yes	Yes	N/A
Contact with the patient	No	No	N/A
Control of life supporting devices	No	No	N/A
Human intervention for image interpretation	Yes	Yes	N/A

Manufacturer	510(K) Submitter	Predicate	Significant Differences
	Peek Health, S.A.	**Orthocrat, Ltd**	
Device Trade Name	**PeekMed**	**TraumaCad version 2.0**	
Ability to add additional modules when available	Yes	Yes	N/A

9. Non-Clinical Performance Data

Results from internal verification and validation testing performed in accordance with Peek Health' design control processes confirm that PeekMed product specifications have been met. Acceptance criteria were achieved for all tests. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device.

Verification testing consisted of specific software functionalities testing and system level testing. Acceptance criteria, defined in the product requirements, were met for each verification test and are described in JIRA. A risk analysis in accordance with ISO 14971 was completed as part of the software design and development effort.

Validation activities for the subject device consisted of:

- Validation tests performed internally prior to the release to the market by qualified personnel (personnel with background in anatomy and biomedical field), 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 Confluence sheets. To reassure that the lengths and angles measured with the internal functions of '*ruler*' and '*angle*' of the PeekMed software effectively and repeatedly match the real dimensions, validation consists the measuring of images of three implantable medical devices (prosthesis), CE marked and with strictly defined dimensions. Validation phase ensures that all product requirements have been fulfilled, meets the end-users needs, and ensure the safety and proper performance of the device.
- As a complementary validation, external validation is performed through a continuous follow-up from the Marketing and Sales team, follow-up on events registered in the platform mixpanel and user/customer surveys. Also, satisfaction questionnaires were made to assess the usability of the PeekMed software when comparing with others in the market, and also to make sure that the device operates as intended during the design stage.

10. Statement of Substantial Equivalence

PeekMed, as designed and developed by Peek Health, S.A., is determined to be substantially equivalent to the predicate device. Differences between the two devices do not raise new questions about the safety and effectiveness of PeekMed.