



Genesis Software Innovations
% Mr. Matt Miller
Director of Technology Development
220 Lyon St NW Suite 500
GRAND RAPIDS MI 49503

April 21, 2021

Re: K210556

Trade/Device Name: Preview Shoulder
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: February 16, 2021
Received: February 25, 2021

Dear Mr. Miller:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K210556

Device Name

Preview Shoulder

Indications for Use (Describe)

The Preview Shoulder software is intended to be used as a tool for orthopedic surgeons to develop pre-operative shoulder plans based on a patient CT imaging study.

The import process allows the user to select a DICOM CT scan series from any location that the user's computer sees as an available file source.

3D digital representations of various implant models are available in the planning software. Preview Shoulder allows the user to digitally perform the surgical planning by showing a representation of the patient's shoulder anatomy as a 3D model and allows the surgeon to place the implant in the patient's anatomy.

The software allows the surgeon to generate a report, detailing the output of the planning activity.

Experience in usage and a clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.

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 **K210556**

Date Prepared: February 16, 2021

Submitter: Genesis Software Innovations
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Contact: Matt Miller
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Proprietary Name: Preview Shoulder

Common Name: Pre-operative planning software

Classifications: 21 CFR Section 892.2050 – Picture archiving and communications system; Class II
Product Code: QIH

Classification Panel: Radiology

Substantially Equivalent Devices: Peek Health, S.A. PeekMed (K182464)

Reference Device: Pixmeo SARL, Osirix MD (K101342)

Intended Use / Indications:

The Preview Shoulder software is intended to be used as a tool for orthopedic surgeons to develop pre-operative shoulder plans based on a patient CT imaging study.

The import process allows the user to select a DICOM CT scan series from any location that the user's computer sees as an available file source.

3D digital representations of various implant models are available in the planning software. Preview Shoulder allows the user to digitally perform the surgical planning by showing a representation of the patient's shoulder anatomy as a 3D model and allows the surgeon to place the implant in the patient's anatomy.



The software allows the surgeon to generate a report, detailing the output of the planning activity.

Experience in usage and a clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.

Device Description:

The Preview Shoulder, a 3D total shoulder arthroplasty (TSA) surgical planning software, is a standalone software application which assists the surgeon in planning reverse and anatomic shoulder arthroplasty. Preview Shoulder includes 3D digital representations of implants for placement in images used for surgical planning. Preview Shoulder is a secure software application used by qualified or trained surgeons and is accessed by authorized users.

The primary function of Preview Shoulder is to receive and process DICOM CT image(s) of patients. Preview Shoulder can be used to place an implant in the original CT image and place an implant in the 3D model of reconstructed bone. The Preview Shoulder allow the user to perform surgical planning and generate an output surgical report. Preview Shoulder does not provide a diagnosis or surgical recommendation. The surgeon is responsible for selecting and placing the implant model for pre-surgical planning purposes.

Substantial Equivalence Discussion:

The proposed Preview Shoulder and its predicate device, PeekMed (K182464), are similar with regards to their intended use, clinical indications, principle of operation and fundamental technology. In conclusion, Genesis Software Innovations believes that the Preview Shoulder does not introduce any new potential safety and/or effectiveness issues and is comparable to the identified predicate device, PeekMed (K182464).

Property or Characteristic	Proposed Device Preview Shoulder	Peek Health, S.A. PeekMed (K182464)	Significant Differences
Product Code	QIH	LLZ	<p>The QIH device definition applies to picture archiving and communications systems that implement artificial intelligence (AI) including nonadaptive machine learning algorithms.</p> <p>Preview Shoulder utilizes an AI algorithm for reconstructing 3D bone model from the image data.</p>
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	N/A
Intended Use	Preoperative planning software for surgery	Preoperative planning software for surgery	N/A
Indications for use	<p>The Preview Shoulder software is intended to be used as a tool for orthopedic surgeons to develop pre-operative shoulder plans based on a patient CT imaging study.</p> <p>The import process allows the user to select a DICOM CT scan series from any location that the user's computer sees as an available file source.</p>	<p>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</p>	<p>The indications for use are similar between the Preview Shoulder and the predicate device.</p>

	<p>3D digital representations of various implant models are available in the planning software. Preview Shoulder allows the user to digitally perform the surgical planning by showing a representation of the patient's shoulder anatomy as a 3D model and allows the surgeon to place the implant in the patient's anatomy.</p> <p>The software allows the surgeon to generate a report, detailing the output of the planning activity.</p> <p>Experience in usage and a clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.</p>	<p>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.</p>	
<p>Subspecialties</p>	<p>Preview Shoulder allows the surgeon to perform the pre-surgical planning for the following subspecialty:</p> <p>Upper Limb: Total Shoulder Replacement</p>	<p>PeekMed allows the surgeon to perform the pre-surgical planning efficiently in the following subspecialties:</p> <ul style="list-style-type: none"> - Hip - Knee - Spine - Upper Limb - Foot and Ankle 	<p>Both devices are designed for pre-surgical planning of total shoulder replacement surgeries.</p> <p>The predicate device is designed for additional pre-surgical planning procedures beyond total shoulder replacement.</p>

		<p>- Trauma</p> <p>For each subspecialty, there are several procedures:</p> <p>-Hip: Hip Dysplasia Correction, Limb Length Discrepancy, Center of Rotation – Ranawat method, Acetabular Angle, Total Hip Arthroplasty</p> <p>-Knee: Leg Deformity Correction, AP Knee Resection, AP Full Leg resection, High Tibial Osteotomy, ACL Tunnel Reconstruction, Medial Patellofemoral Ligament</p> <p>-Spine: Single Cobb Angle, Thoracic Kyphosis Angle, Lumbar Lordosis Angle, Sagittal Vertical Axis, Pelvic Angles, Coronal Balance, Sacrofemoral Angle, Sagittal Balance, Smith-Petersen Osteotomy, Pedicle Subtraction Osteotomy</p> <p>-Upper Limb: Total Shoulder Replacement, Clavicular Angle, Shoulder Resurfacing</p> <p>-Foot and Ankle: Talar Tilt, Hallux Valgus, Moreau-Costa-Bertani Internal Angle, MoreauCosta-</p>	<p>Preview Shoulder has been validated for pre-surgical planning of total shoulder replacement surgeries.</p> <p>The limitation of pre-surgical planning subspecialties does not raise new questions of safety or effectiveness.</p>
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		Bertani External Angle, Maestro Formula -Trauma: Diaphyseal Shaft Fracture Angle, Metaphyseal Shaft Fracture Angle, Roof Arc	
Type of Use	Prescription Only	Prescription Only	N/A
Patient Population	Adults	Adults and pediatrics	<p>The Preview Shoulder is intended for use with adult patient images only.</p> <p>Preview Shoulder has been validated using adult patient images.</p> <p>Preview Shoulder's measurement image processing and measurement capabilities of adult CT images does not raise new questions on safety or effectiveness.</p>
End User	Surgeons	Surgeons	N/A
Computer	Personal Computer or Workstation	Personal Computer or Workstation	N/A
Operating System	Windows or MacOS	Windows or OS X	N/A

<p>Device Availability</p>	<p>The software is installed and started from the user's computer.</p>	<p>It can be set to start from a workstation or standalone for planning procedures.</p>	<p>Both the Preview Shoulder and predicate device are accessed through the surgeon's computer system.</p>
<p>Images source</p>	<p>Receives medical images from various sources locally available to the user's computer.</p> <p>Preview Shoulder does not communicate directly to a PACS system.</p>	<p>Receives medical images from various sources (including PACS)</p>	<p>Both devices import image files from multiple data locations. The predicate retrieves files from CD ROM, local file storage, or PACS.</p> <p>The Preview Shoulder does not communicate directly to a PACS system but can retrieve files from any file storage location accessible by the surgeon's computer in DICOM format.</p> <p>The file storage and retrieval location does not raise new questions of safety or effectiveness as the DICOM images can be stored and transferred utilizing any file sharing systems.</p>
<p>Data processing</p>	<p>The software processes the CT image, which allows the implant to be overlapped/ placed in both the original scan images and/or the 3D model reconstruction of the bone for surgical planning.</p>	<p>The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material</p>	<p>Both the Preview Shoulder and predicate device process patient images in order for the surgeon to overlap (place) 3D digital representations of implant models and dimension anatomic features.</p>

			The Preview Shoulder CT image processing has been validated.
Digital overlap of prosthetic material	The software allows the implant rendering to be overlapped/placed in the 3D model reconstruction of the bone that results from the processed CT image(s).	Allows the overlap of models and the intersection of the models	<p>Both the Preview Shoulder and predicate device allow the 3D digital representations of implant models representations to be overlapped (placed) in the processed images.</p> <p>The Preview Shoulder does not include functionality to intersect 3D models of reconstructed bone. Intersection functionality is not necessary for planning of total shoulder replacement surgery.</p> <p>The Preview Shoulder functionality to place 3D digital representations of implant models has been validated.</p>
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	No	Yes	Automatic Calibration refers to the predicate's capability to use standard markers placed in X-ray images to determine scale. Preview Shoulder does not allow single X-ray images for planning and the presence of scaling markers are not used for 3D imaging modalities.
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
Ability to add additional modules when available	Yes	Yes	N/A

Bench Testing:

Software Verification and Validation testing was performed on the Preview Shoulder, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software is considered as a "moderate level of concern" since a failure or latent design flaw could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

The Verification and Validation testing was performed to assess the safety and effectiveness of the device, to demonstrate the processing of patient images to produce accurate and repeatable 3D reconstructed bones and surgical coordinates provided to the surgeon. Testing verified that the system performs as intended. The software has been verified via code reviews and automated and manual testing. The measurement capabilities of the Preview Shoulder were validated to be significantly equivalent to a benchmark tool with CT rendering measurement capabilities, Osirix MD (K101342). All validation testing was performed on a fully configured system using anonymized patient shoulder CT images to emulate intended use. All user features have been validated by surgeons.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of the Preview Shoulder to the predicate device.

Overall Conclusion:

Based on the information presented in this submission, Genesis Software Innovations concludes that the Preview Shoulder is similar to the predicate devices in regard to indications, principles of operation, and technological characteristics. Additionally, verification and validation tests demonstrate the safety and efficacy of the device to meet its intended use and specifications. Genesis Software Innovations believes that the proposed device, Preview Shoulder, is similar to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.