Genesis Software Innovations
Matt Miller
Director of Technology Development
2851 Charlevoix Dr. SE Suite 327
Grand Rapids, MI 49546

April 4, 2024

Re: K240172
Trade/Device Name: Preview Shoulder
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 7, 2024
Received: March 7, 2024

Dear Matt 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 (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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240172

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.

510(k) Summary

Date Prepared:	March 7, 2024
Submitter:	Genesis Software Innovations 2851 Charlevoix Dr. SE Suite 327 Grand Rapids, MI 49546
Contact:	Matt Miller Director of Technology Development Genesis Software Innovations (616) 294-1026 Ext. 5 matt.miller@genesissoftwareinnovations.com
Proprietary Name:	Preview Shoulder
Common Name:	Pre-operative planning software
Classification Name:	Picture archiving and communications system
Regulation Number:	21 CFR Section 892.2050
Classification Code:	QIH
Review Panel:	Radiology
Substantially Equivalent Device:	Genesis Software Innovations, Preview Shoulder (K210556)
Reference Device:	Pixmeo SARL, Osirix MD (K101342)

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.

Indications for Use:

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.

Comparison of Technological Characteristics:

The Preview Shoulder fundamental technological characteristics are similar to those of the predicate device as noted in the following table.

Characteristic	**Proposed Device** Genesis Software Innovations Preview Shoulder (K240172)	**Predicate Device** Genesis Software Innovations Preview Shoulder (K210556)	**Significant Differences**
Product Code	QIH	QIH	N/A
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	The Preview Shoulder software is intended to be	The Preview Shoulder software is intended to be	N/A

	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.	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.	
Subspecialties	Preview Shoulder allows the surgeon to perform the pre-surgical planning for the following subspeciality: Upper Limb: Total Shoulder Replacement	Preview Shoulder allows the surgeon to perform the pre-surgical planning for the following subspeciality: Upper Limb: Total Shoulder Replacement	N/A
Type of Use	Prescription Only	Prescription Only	N/A
Patient Population	Adults	Adults	N/A
End User	Surgeons	Surgeons	N/A
Computer	Personal Computer or Workstation	Personal Computer or Workstation	N/A
Operating System	Windows or MacOS	Windows or MacOS	N/A

Device Availability	The software is installed and started from the user's computer.	The software is installed and started from the user's computer.	N/A
Images source	Receives medical images from various sources locally available to the user's computer. Preview Shoulder does not communicate directly to a PACS system.	Receives medical images from various sources locally available to the user's computer. Preview Shoulder does not communicate directly to a PACS system.	N/A
Data processing	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.	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.	Similar Post-processing algorithm is added to further refine the 3D mesh quality. Algorithm is added to calculate humerus-side features used for implant selection, placement, and pre-surgical planning.
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). The software facilitates the placement and rendering of scapula and humerus implants for anatomic partial or total shoulder arthroplasty and reverse total shoulder arthroplasty.	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). The software facilitates the placement and rendering of scapula implants for anatomic partial or total shoulder arthroplasty and reverse total shoulder arthroplasty.	Similar Humerus implants are added to implant planning library.
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	No	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
Ability to add additional modules when available	Yes	Yes	N/A

Non-Clinical Testing Summary:

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, "Content of Premarket Submissions for Device Software Functions". The software is considered as a "basic documentation level" since a failure or latent design flaw would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures. 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 Summary:

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.