Mighty Oak Medical
Mark Wylie
VP Quality and Regulatory
750 W. Hampden Ave
Suite 120
Englewood, Colorado 80110

July 12, 2024

Re: K234009
Trade/Device Name: Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: June 12, 2024
Received: June 12, 2024

Dear Mark Wylie:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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.

510(k) Number *(if known)*
K234009

Device Name
Acorn 3D Software (AC-SEG-4009)
Acorn 3DP Model (AC-101-XX)

Indications for Use *(Describe)*
Acorn Segmentation is intended for use as a software interface and image segmentation system for the transfer of CT or CTA medical images to an output file. Acorn Segmentation is also intended for measuring and treatment planning. The Acorn Segmentation output can also be used for the fabrication of physical replicas of the output file using additive manufacturing methods, Acorn 3DP Models. The physical replica can be used for diagnostic purposes in the field of musculoskeletal and craniomaxillofacial applications.
Acorn Segmentation and 3DP Models should be used in conjunction with expert clinical judgment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY **K234009**

Acorn 3D Software (AC-SEG-4009) and Acorn 3DP Model (AC-101-XX)

Submitter:

Mighty Oak Medical
750 W. Hampden Ave., Suite 120
Englewood, CO 80110
(720) 398-9703

Contact: Mark A. Wylie, VP of Quality and Regulatory

Date Prepared: 12JUL2024

Device

Trade Name: Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)
Common Name: Image processing system
Device Classification: Class II
Regulation, Name: 21 CFR 892.2050, Medical image management and processing system
Device Product Code: QIH, LLZ

Type of 510(k)

Original Submission: Traditional

Predicate Device(s):

Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K183105	LLZ	Mimics Medical	Materialise NV
Subsequent Predicate Device			
K183489	LLZ	D2P	3D Systems, Inc

Description

Acorn Segmentation is an image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models. The models can be used in Acorn Segmentation for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). Acorn Segmentation is structured as a modular package. This includes the following functionality:

- Importing medical images in DICOM format
- Viewing images and DICOM data
- Selecting a region of interest using generic segmentation tools
- Segmenting specific anatomy using dedicated semi-automatic tools or automatic algorithms
- Verifying and editing a region of interest
- Calculating a digital 3D model and editing the model
- Measuring on images and 3D models
- Exporting 3D models to third-party packages

Acorn Segmentation contains both machine learning based auto-segmentation as well as semi-automatic and manual segmentation tools. The auto-segmentation tool is only intended to be used for thoracic and lumbar regions of the spine (T1-T12 and L1-L5). Semi-automatic and manual segmentation tools are intended to be used for all musculoskeletal and craniomaxillofacial anatomy. The following table provides a definition and the anatomical location(s) for each tool's intended use.

	Automatic	Semi-Automatic	Manual
Definition	Algorithmic with little or no direct human control	A combination of algorithmic and direct human control	Directly controlled by a human
Tool Type	Machine Learning algorithm used to automatically segment individual vertebrae	Algorithmic based tools that do not incorporate machine learning.	Manual tools requiring user input.
Anatomical Location (s)	Spinal anatomy: • Thoracic (T1-T12) • Lumbar (L1-L5)	Musculoskeletal & craniomaxillofacial bone: • Short • Long • Flat • Sesamoid • Irregular	Musculoskeletal & craniomaxillofacial bone: • Short • Long • Flat • Sesamoid • Irregular

Acorn 3DP Model is an additively manufactured physical replica of the digital 3D model generated in Acorn Segmentation. The output file from Acorn Segmentation is used to additively manufacture the Acorn 3DP Model.

Indications for Use

Acorn Segmentation is intended for use as a software interface and image segmentation system for the transfer of CT or CTA medical images to an output file. Acorn Segmentation is also intended for measuring and treatment planning. The Acorn Segmentation output can also be used for the fabrication of physical replicas of the output file using additive manufacturing methods, Acorn 3DP Models. The physical replica can be used for diagnostic purposes in the field of musculoskeletal and craniomaxillofacial applications.

Acorn Segmentation and 3DP Models should be used in conjunction with expert clinical judgment.

Materials

Acorn 3DP materials used have been tested and shown to be biocompatible in accordance with ISO 10993-1. The material used to manufacture Acorn 3DP Models is a PA-12 polymer powder for use in HP multi-jet fusion systems.

Performance Data

Software verification and validation were performed and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This includes verification against defined requirements, and validation against user needs. Both end-user validation and bench testing were performed.

The geometric accuracy of digital models created in the subject device, Acorn Segmentation, was assessed via bench testing of automatic, semi-automatic, and manual segmentation methods. Accuracy of automatic segmentation was evaluated for its intended use on Thoracic (T1-T12) and Lumbar (L1-L5) anatomy. Accuracy of semi-automatic and manual segmentation methods was evaluated for their intended for use on musculoskeletal and craniomaxillofacial anatomy. All segmentations were evaluated against predicate device segmentations using Dice-Sorenson coefficient. Testing of automatic, semi-automatic, and manual segmentation methods each exceeded an average Dice-Sorenson coefficient of 0.93. All deviations were within the acceptance criteria. This shows that for creating digital models, Acorn Segmentation is substantially equivalent to the predicate device.

The geometric accuracy of physical replicas (produced by 3D printing digital models) was also assessed. This was conducted for various representative musculoskeletal and craniomaxillofacial models. Testing showed that the physical models can be printed accurately at less than 1mm mean deviation when compared to the digital models.

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.

Technological Characteristics

The following technological characteristics of the subject Acorn Segmentation & 3DP Model are equivalent to the predicate devices. These include:

- Importing medical images in DICOM format
- Viewing images and DICOM data
- Selecting a region of interest using generic segmentation tools
- Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms
- Verifying and editing a region of interest
- Calculating a digital 3D model and editing the model
- Measuring on images and 3D models
- Exporting 3D models to third-party packages

Technological characteristics which are different have been supported with descriptive information and/or performance data. Therefore the fundamental scientific technology of Acorn Segmentation & 3DP Model is the same as the previously cleared device.

Substantial Equivalence Comparison Table

The table below provides a descriptive comparison of the similarities and differences for the subject and predicate devices. The items marked **bold** in the table highlight the differences between the Acorn Segmentation & 3DP Model and the predicate (Materialise's Mimics Medical, K183105).

Device→ **Features↓**	**Acorn Segmentation** (K234009)	**Mimics Medical** (K183105)	**D2P** (K183489)
Premarket notification	K234009	K183105	K183489
Manufacturer	Mighty Oak Medical	Materialise N.V.	3D Systems
Indications for Use Statement	**Acorn Segmentation** is intended for use as a software interface and image segmentation system for the transfer of **CT or CTA** medical imaging information to an output file. **Acorn Segmentation** is also intended for measuring and treatment planning. The **Acorn Segmentation** output can also be used for the fabrication of physical replicas of the output file using additive manufacturing methods, **Acorn 3DP Models**. The physical replica can be used for diagnostic purposes in the field of **musculoskeletal and craniomaxillofacial** applications. **Acorn Segmentation and 3DP Models** should be used in conjunction with expert clinical judgment.	**Mimics** is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. **Mimics Medical** is also intended for measuring and treatment planning. The **Mimics Medical** output can be used for the fabrication of physical replicas of the output file using **traditional or** additive manufacturing methods. **The physical replica can be used for diagnostic purposes in**	**The D2P** software is intended for use as a software interface and image segmentation system for the transfer of **DICOM imaging** information **from a medical scanner** to an output file. **It** is also intended as **pre-operative software for surgical planning**. **For this purpose,** the output file may be used **to produce a** physical replica. **The physical replica is intended for adjunctive use along with other diagnostic tools and expert clinical judgement for**

Device→ **Features↓**	**Acorn Segmentation** (K234009)	**Mimics Medical** (K183105)	**D2P** (K183489)
		the field of orthopaedic, maxillofacial and cardiovascular applications. **Mimics Medical** should be used in conjunction with expert clinical judgment.	**diagnosis, patient management, and/or treatment selection of cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.**
General intended use	**Acorn Segmentation** is image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models.	**Mimics Medical** is image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models.	**D2P** is image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models.
Product Classification	System, Image processing, Radiological	System, Image processing, Radiological	System, Image processing, Radiological
Regulatory Class	Class II	Class II	Class II
Regulation Number	892.2050	892.2050	892.2050
Product Code	QIH, LLZ	LLZ	LLZ
Device Description	**Acorn Segmentation** is an image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models. The models can be used in **Acorn Segmentation** for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). **Acorn Segmentation** is structured as a modular package. This includes the following functionality: • Importing medical images in DICOM format • Viewing images and DICOM data • Selecting a region of interest using generic segmentation tools • Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms • Verifying and editing a region of interest • Calculating a digital 3D model and editing the model • Measuring on images and 3D models • Exporting 3D models to third-party packages **Acorn Segmentation contains both machine learning based auto-segmentation as well as semi-automatic and manual segmentation tools. The auto-segmentation tool is only intended to be used for thoracic and lumbar regions of the spine (T1-T12 and L1-L5). Semi-automatic and manual segmentation tools are intended to be used for all musculoskeletal and craniomaxillofacial anatomy. The following table provides a definition**	**Mimics Medical** is image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models. The models can be used in **Mimics Medical** for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). **Mimics Medical also has functionality for linking to third party software packages. Mimics Medical** is structured as a modular package. This includes the following functionality: • Importing medical images in DICOM format **and other formats (such as**	**The D2P software is a stand-alone modular software package that provides advanced visualization of DICOM imaging data. This modular package includes, but is not limited to the following functions:** • **DICOM viewer and analysis** • **Automated segmentation** • **Editing and pre-printing** • **Seamless integration with 3D Systems printers** • **Seamless integration with 3D Systems software packages** • **Seamless integration with Virtual Reality visualization for non-diagnostic use.**

<table>
<tr><th>Device→
Features↓</th><th>Acorn Segmentation
(K234009)</th><th>Mimics Medical
(K183105)</th><th>D2P
(K183489)</th></tr>
<tr>
<td></td>
<td>
and the anatomical location(s) for each tool's intended use.
<table>
<tr><th></th><th>Automatic</th><th>Semi-Automatic</th><th>Manual</th></tr>
<tr><td>Definition</td><td>Algorithmic with little or no direct human control</td><td>A combination of algorithmic and direct human control</td><td>Directly controlled by a human</td></tr>
<tr><td>Tool Type</td><td>Machine Learning algorithm used to automat-ically segment individual vertebrae</td><td>Algorithmic based tools that do not incorporate machine learning.</td><td>Manual tools requiring user input.</td></tr>
<tr><td>Anatom-ical Location (s)</td><td>Spinal anatomy:
• Thoracic (T1-T12)
• Lumbar (L1-L5)</td><td>Musculo-skeletal & cranioma-xillofacial bone:
• Short
• Long
• Flat
• Sesamoid
• Irregular</td><td>Musculo-skeletal & craniuma-xillofacial bone:
• Short
• Long
• Flat
• Sesa-moid
• Irreg-ular</td></tr>
</table>
Acorn 3DP Model is an additively manufactured physical replica of the virtual 3D model generated in Acorn Segmentation. The output file from Acorn Segmentation is used to additively manufacture the Acorn 3DP Model.
</td>
<td>
BMP, TIFF, JPG and raw images)
• Viewing images and DICOM data
• Selecting a region of interest using generic segmentation tools
• Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms
• Verifying and editing a region of interest
• Calculating a digital 3D model and editing the model
• Measuring on images and 3D models
• Exporting images, measurements and 3D models to third-party packages
• Planning treatments (surgical cuts etc.) on the 3D models
• Interfacing with packages for Finite Element Analysis
• Creating Python scripts to automate workflows
</td>
<td></td>
</tr>
<tr>
<td>Technological characteristics</td>
<td>
Acorn Segmentation is a standalone modular software package. This module includes, but is not limited to the following functions:
<u>Image Import</u>
• Importing medical images in DICOM format
<u>Image Processing</u>
• Processing of images with common noise-reduction filters
• Editing of spatial arrangement of images
<u>Visualization</u>
• Viewing images and DICOM data
<u>Segmentation</u>
• Selecting a region of interest using generic segmentation tools
• Segmenting specific anatomy using dedicated semi-automatic tools
</td>
<td>
Mimics Medical is structured as a modular package. This includes the following functionality:
<u>Image Import</u>
• Importing medical images in DICOM format and other formats (such as BMP, TIFF, JPG and raw images)
<u>Image Processing</u>
• Processing of images with common noise-reduction filters
</td>
<td>
D2P is structured as a modular package. This includes the following functionality:
<u>Image Import</u>
• Importing medical images in DICOM format and other formats (such as BMP, TIFF, JPG and raw images)
<u>Image Processing</u>
• Processing of images with common noise-reduction filters
</td>
</tr>
</table>

Device→ Features↓	**Acorn Segmentation** (K234009)	**Mimics Medical** (K183105)	**D2P** (K183489)
	• Segmenting specific **vertebral** anatomy using **machine-learning-based** fully automatic algorithms • Verifying and editing a region of interest <u>Measurement</u> • Measuring on images and 3D models <u>Image Export</u> • Exporting images and 3D models to third-party packages <u>3D Models</u> • Calculating a digital 3D model and editing the model • Smoothing a 3D model • Importing 3D models <u>Treatment Planning</u> • Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images <u>Other features</u> • **Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm**	• Editing of spatial arrangement of images • **Processing of imaging data for removal of common artifacts (e.g. scatter)** <u>Visualization</u> • Viewing images and DICOM data <u>Segmentation</u> • Selecting a region of interest using generic segmentation tools • Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms • Verifying and editing a region of interest <u>Measurement</u> • Measuring on images and 3D models <u>Image Export</u> • Exporting images, **measurements** and 3D models to third-party packages <u>3D Models</u> • Calculating a digital 3D model and editing the model • **Wrapping a 3D model** • Smoothing a 3D model • Importing 3D models <u>Treatment Planning</u> • Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images • **Planning treatments (surgical cuts etc.) on the 3D models**	• Editing of spatial arrangement of images <u>Visualization</u> • Viewing images and DICOM data <u>Segmentation</u> • Selecting a region of interest using generic segmentation tools • Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic **deep learning tools** • Verifying and editing a region of interest <u>Measurement</u> • Measuring on images and 3D models <u>Image Export</u> • Exporting images and 3D models to third-party packages <u>3D Models</u> • Calculating a digital 3D model and editing the model • Smoothing a 3D model • Importing 3D models <u>Treatment Planning</u> • Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images • **Planning treatments (surgical cuts etc.) on the 3D models** <u>Other features</u> **View DICOM images in VR without segmentation**

Device→ Features↓	Acorn Segmentation (K234009)	Mimics Medical (K183105)	D2P (K183489)
		Other features • **Interfacing with packages for Finite Element Analysis** • **Creating Python scripts to automate workflows**	
Physical Model	The **Acorn Segmentation** output can be used for the fabrication of physical replicas of the output file using additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of **musculoskeletal and craniomaxillofacial** applications.	The **Mimics Medical** output can be used for the fabrication of physical replicas of the output file using **traditional** or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopedic, **maxillofacial and cardiovascular** applications.	The D2P output file may be used to produce a physical replica. The physical replica is intended for **adjunctive use** along with other diagnostic tools and expert clinical judgement for diagnosis, **patient management**, and/or **treatment selection** of **cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or** musculoskeletal applications.

Conclusion

Minor differences in intended use and technological characteristics exist, but performance data demonstrates that Acorn Segmentation & 3DP Model is as safe and effective, and performs as well as the predicate device for its intended use.