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

June 11, 2026

Re: K260322
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: May 8, 2026
Received: May 8, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb

Jessica Lamb
Assistant Director, Ph.D
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260322

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

Acorn 3D Software is a modular image processing software intended for use as an interface for visualization of medical images, segmentation, anatomical measurements, treatment planning, treatment simulation, and production of an output file.
The Acorn 3D Segmentation module is intended for use as a software interface and image segmentation system for the transfer of CT, sCT, or CTA medical images to an output file. Acorn 3D Segmentation is also intended for measuring and treatment planning. The Acorn 3D 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.
The Acorn 3D Alignment and Measurement module contains registration capabilities and measurement functionality based on anatomical reference geometry. It is intended to allow the user to align anatomical structures between datasets, perform spinopelvic measurements on 3D models of anatomy, and plan surgical procedures in pediatric and adult patients.
The Acorn 3D Trajectory Automation module may be used to plan pedicle screw placement in the thoracic and lumbar regions of the spine in pediatric and adult patients.
The Acorn 3D Correction module may be used to plan and simulate aspects of surgical procedures in pediatric and adult patients.
Acorn 3D Software and 3DP Models should be used in conjunction with expert clinical judgment.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Acorn 3D Software

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: 30JAN2026

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 & 3DP Model

510(k)	Product Code	Trade Name	Manufacturer
Predicate Device			
K252103	QIH, LLZ	Acorn 3D Software & 3DP Model	Mighty Oak Medical
Reference Devices			
K251532	QIH, LLZ	Acorn 3D Software & 3DP Model	Mighty Oak Medical
K141669	LLZ	Surgimap	Nemaris
K213975	LLZ	KEOPS Balance Analyzer 3D	S.M.A.I.O.

Introduction

This 510(k) filing seeks to expand the indications for use of the previously cleared Acorn 3D Software (K252103) to include registration capabilities and measurement functionality based on anatomical reference geometry. This submission includes the Acorn 3D Correction module as a new extension of the Acorn 3D Software.

Acorn 3D Software is a modular and multi-functional software suite. The subject device, Acorn 3D Correction module, builds on the functions and capabilities of the Acorn 3D Software (predicate), specifically image segmentation and the transfer of imaging information from a

medical scanner to an output file. Acorn 3D Correction module allows the user to plan and simulate aspects of surgical procedures.

Description

Acorn 3D Software 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 3D Software for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). Acorn 3D Software 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
- Image registration
- Planning pedicle screw placement
- Treatment Simulation

The Acorn 3D Segmentation module 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) and the pelvis (sacrum). Semi-automatic and manual segmentation tools are intended to be used for all musculoskeletal anatomy.

	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 and the pelvis	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) • Sacrum	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 virtual 3D model generated in Acorn 3D Segmentation. The output file from Acorn 3D Segmentation is used to additively manufacture the Acorn 3DP Model.

The Acorn 3D Alignment and Measurement module contains registration capabilities and spinopelvic measurement functionality. It is intended to align spinopelvic anatomical structures between datasets. The module allows the user to perform spinopelvic measurements on 3D models of anatomy, and to plan surgical procedures.

The Acorn 3D Trajectories module contains dedicated fully automatic algorithms for planning pedicle screw trajectories. The algorithms are only intended to be used for the thoracic and

lumbar regions of the spine (T1-T12 and L1-L5). The output file from Acorn 3D Trajectory Automation contains information relevant to pedicle screw placement surgery, including entry points, end points, and screw sizes of planned screws.

The Acorn 3D Correction module contains tools for pre-operative planning and treatment simulation.

Indications for Use

Acorn 3D Software is a modular image processing software intended for use as an interface for visualization of medical images, segmentation, anatomical measurements, treatment planning, treatment simulation, and production of an output file.

The Acorn 3D Segmentation module is intended for use as a software interface and image segmentation system for the transfer of CT, sCT, or CTA medical images to an output file. Acorn 3D Segmentation is also intended for measuring and treatment planning. The Acorn 3D 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.

The Acorn 3D Alignment and Measurement module contains registration capabilities and measurement functionality based on anatomical reference geometry. It is intended to allow the user to align anatomical structures between datasets, perform spinopelvic measurements on 3D models of anatomy, and plan surgical procedures in pediatric and adult patients.

The Acorn 3D Trajectory Automation module may be used to plan pedicle screw placement in the thoracic and lumbar regions of the spine in pediatric and adult patients.

The Acorn 3D Correction module may be used to plan and simulate aspects of surgical procedures in pediatric and adult patients.

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

Materials

The manufactured components of the Acorn 3DP Model are manufactured from a polymer powder for use in additive manufacturing (HP 3D High Reusability PA12).

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 clinical acceptability of simulated treatment planning generated by the Acorn 3D Correction module was evaluated through bench testing. Testing demonstrated that the system reliably produced simulated corrections that met surgeon-defined inputs, including achievement of target angular metrics within 3°. Intra- and inter-observer variability were also assessed, with results demonstrating less than 3° of variability as measured by mean absolute difference and two times the standard deviation (2×SD), representing approximately 95% of observations.

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

Technological Characteristics

Acorn 3D Software is a standalone modular software package. This software package includes, but is not limited to, the following functions:

Image Import
- Importing medical images in DICOM format

Image Processing
- Processing of images with common noise-reduction filters
- Editing of spatial arrangement of images

Visualization
- Viewing images and DICOM data

Segmentation
- Selecting a region of interest using generic segmentation tools
- Segmenting specific anatomy using dedicated semi-automatic tools
- Segmenting specific vertebral anatomy using machine-learning-based fully automatic algorithms
- Verifying and editing a region of interest

Image Export
- Exporting images and 3D models to third-party packages

3D Models
- Calculating a digital 3D model and editing the model
- Smoothing a 3D model
- Importing 3D models

Registration
- Alignment of anatomical structures between datasets

Measurement
- Measuring on images and 3D models
- Standard and generic 3D measurements of spinopelvic anatomy based on user-defined reference geometry

Treatment Planning
- Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images
- Pedicle Screw Placement
- Simulation of anatomy in a corrected configuration

Other features
- Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm

Substantial Equivalence Comparison Table

Device→ Features↓	**Acorn 3D Software** (this submission)	**Acorn 3D Software** (K252103)
Trade Name	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)
Common Name	Image processing system	Image processing system
Premarket notification	*Not yet submitted*	K252103
Manufacturer	Mighty Oak Medical	Mighty Oak Medical
Indications for Use Statement	Acorn 3D Software is a modular image processing software intended for use as an interface for visualization of medical images, segmentation, **anatomical measurements,** treatment planning, **treatment simulation,** and production of an output file. The Acorn 3D Segmentation module is intended for use as a software interface and	Acorn 3D Software is a modular image processing software intended for use as an interface for visualization of medical images, segmentation, treatment planning, and production of an output file. The Acorn 3D Segmentation module is intended for use as a software interface and

Device→ **Features↓**	**Acorn 3D Software** (this submission)	**Acorn 3D Software** (K252103)
	image segmentation system for the transfer of CT, sCT, or CTA medical images to an output file. Acorn 3D Segmentation is also intended for measuring and treatment planning. The Acorn 3D 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. The Acorn 3D Alignment and Measurement module contains registration capabilities and measurement functionality based on anatomical reference geometry. It is intended to allow the user to align anatomical structures between datasets, perform spinopelvic measurements on 3D models of anatomy, and plan surgical procedures in pediatric and adult patients. The Acorn 3D Trajectory Automation module may be used to plan pedicle screw placement in the thoracic and lumbar regions of the spine in pediatric and adult patients. **The Acorn 3D Correction module may be used to plan and simulate aspects of surgical procedures in pediatric and adult patients.** Acorn 3D Software and 3DP Models should be used in conjunction with expert clinical judgment.	image segmentation system for the transfer of CT or CTA medical images to an output file. Acorn 3D Software is also intended for measuring and treatment planning. The Acorn 3D 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. The Acorn 3D Alignment and Measurement module contains registration capabilities and measurement functionality based on anatomical reference geometry. It is intended to allow the user to align anatomical structures between datasets, perform spinopelvic measurements on 3D models of anatomy, and plan surgical procedures in pediatric and adult patients. The Acorn 3D Trajectory Automation module may be used to plan pedicle screw placement in the thoracic and lumbar regions of the spine in pediatric and adult patients. Acorn 3D Software and 3DP Models should be used in conjunction with expert clinical judgment.
General intended use	Acorn 3D Software is an image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, conduct surgical planning, and create and manipulate digital 3D models.	Acorn 3D Software is an image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, conduct surgical planning, and create and manipulate digital 3D models.
Product Classification	System, Image processing, Radiological	System, Image processing, Radiological
Regulatory Class	Class II	Class II
Classification	892.2050	892.2050
Product Code	QIH and LLZ	QIH and LLZ
Device Description	Acorn 3D Software 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 3D for measuring, treatment planning, **treatment simulation,** and producing an output file to be used for additive manufacturing (3D printing). Acorn 3D Software is structured as a modular package. This includes the following functionality: • Importing medical images in DICOM format • Viewing images and DICOM data	Acorn 3D Software 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 3D for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). Acorn 3D Software is structured as a modular package. This includes the following functionality: • Importing medical images in DICOM format • Viewing images and DICOM data

Device→ **Features↓**	**Acorn 3D Software** (this submission)	**Acorn 3D Software** (K252103)
	• 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 • Image registration • Planning pedicle screw placement plan • **Treatment Simulation** The Acorn 3D Segmentation module 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 anatomy. Acorn 3DP Model is an additively manufactured physical replica of the virtual 3D model generated in Acorn 3D Segmentation. The output file from Acorn 3D Segmentation is used to additively manufacture the Acorn 3DP Model. The Acorn 3D Alignment and Measurement module contains registration capabilities and spinopelvic measurement functionality. It is intended to align spinopelvic anatomical structures between datasets. The module allows the user to perform spinopelvic measurements on 3D models of anatomy, and to plan surgical procedures. The Acorn 3D Trajectories module contains dedicated fully automatic algorithms for planning pedicle screw trajectories. The algorithms are only intended to be used for the thoracic and lumbar regions of the spine (T1-T12 and L1-L5). The output file from Acorn 3D Trajectory Automation contains information relevant to pedicle screw placement surgery, including entry points, end points, and screw sizes of planned screws. **The Acorn 3D Correction module contains tools for pre-operative planning and treatment simulation.**	• 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 • Image registration • Planning pedicle screw placement plan The Acorn 3D Segmentation module 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 anatomy. Acorn 3DP Model is an additively manufactured physical replica of the virtual 3D model generated in Acorn 3D Segmentation. The output file from Acorn 3D Segmentation is used to additively manufacture the Acorn 3DP Model. The Acorn 3D Alignment and Measurement module contains registration capabilities and spinopelvic measurement functionality. It is intended to align spinopelvic anatomical structures between datasets. The module allows the user to perform spinopelvic measurements on 3D models of anatomy, and to plan surgical procedures. The Acorn 3D Trajectories module contains dedicated fully automatic algorithms for planning pedicle screw trajectories. The algorithms are only intended to be used for the thoracic and lumbar regions of the spine (T1-T12 and L1-L5). The output file from Acorn 3D Trajectory Automation contains information relevant to pedicle screw placement surgery, including entry points, end points, and screw sizes of planned screws.
Intended User	The Acorn 3D Segmentation module can be used by biomedical engineers or personnel equivalent by training or experience. Their results should be used in conjunction with expert clinical judgement. The Acorn 3D **Alignment & Measurement, Trajectory Automation, and Correction**	The Acorn 3D Segmentation module can be used by biomedical engineers or personnel equivalent by training or experience. Their results should be used in conjunction with expert clinical judgement. The Acorn 3D **Alignment & Measurement module is intended** for use by medical

Device→ **Features↓**	**Acorn 3D Software** (this submission)	**Acorn 3D Software** (K252103)
	modules are intended for use by medical professionals, such as clinicians and surgeons, who are trained in spinal procedures and the interpretation of diagnostic imaging.	professionals, such as clinicians and surgeons, who are trained in spinal procedures and the interpretation of diagnostic imaging. The Acorn 3D **Trajectory Automation module is intended** for use by medical professionals, such as clinicians and surgeons, who are trained in spinal procedures and the interpretation of diagnostic imaging.
Technological characteristics	Acorn 3D Software is a standalone modular software package. This software package 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 • Segmenting specific vertebral anatomy using machine-learning-based fully automatic algorithms • Verifying and editing a region of interest <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>Registration</u> • Alignment of anatomical structures between datasets <u>Measurement</u> • Measuring on images and 3D models • Standard and generic 3D measurements of spinopelvic anatomy based on user-defined reference geometry <u>Treatment Planning</u> • Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images • Pedicle screw placement • **Simulation of anatomy in a corrected configuration** <u>Other features</u>	Acorn 3D Software is a standalone modular software package. This software package 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 • Segmenting specific vertebral anatomy using machine-learning-based fully automatic algorithms • Verifying and editing a region of interest <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>Registration</u> • Alignment of anatomical structures between datasets <u>Measurement</u> • Measuring on images and 3D models • Standard and generic 3D measurements of spinopelvic anatomy based on user-defined reference geometry <u>Treatment Planning</u> • Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images • Pedicle screw placement <u>Other features</u>

Device→ Features↓	Acorn 3D Software (this submission)	Acorn 3D Software (K252103)
	• Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm	• Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm
Machine-Learning Algorithms	The Acorn 3D Segmentation module automates the segmentation of particular anatomy (listed in IFU) by implementing a 3D U-Net machine learning model. Segmentation of the images is completed by generating an input image that is preprocessed (image processing methods) and then is run through an analysis (encoder) path and a synthesis (decoder) path. When the image is going through the analysis path, the model is learning by focusing on new information presented and by dynamically learning which information from the image is the most useful. The image then goes through the synthesis path in which the model recovers spatial resolution and focus on salient features that the analysis path coded. The parameters of the model were obtained through an algorithm development pipeline.	The Acorn 3D Segmentation module automates the segmentation of particular anatomy (listed in IFU) by implementing a 3D U-Net machine learning model. Segmentation of the images is completed by generating an input image that is preprocessed (image processing methods) and then is run through an analysis (encoder) path and a synthesis (decoder) path. When the image is going through the analysis path, the model is learning by focusing on new information presented and by dynamically learning which information from the image is the most useful. The image then goes through the synthesis path in which the model recovers spatial resolution and focus on salient features that the analysis path coded. The parameters of the model were obtained through an algorithm development pipeline.
Machine-Learning Models	Acorn 3D Segmentation • Vertebral model (T1-T12, L1-L5) • Sacral model	Acorn 3D Segmentation • Vertebral model (T1-T12, L1-L5) • Sacral model
Bone Model	The Acorn 3D 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 and/or intraoperative reference of anatomy in the field of orthopedic and musculoskeletal applications.	The Acorn 3D 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 and/or intraoperative reference of anatomy in the field of orthopedic and musculoskeletal applications.

Predetermined Change Control Plan (cleared as part of K234009)

The Acorn 3D Software uses an algorithm derived from machine learning (ML) to segment bony anatomy from CT or CTA images. Mighty Oak Medical will make future algorithm improvements under a Predetermined Change Control Plan (PCCP; cleared as part of K234009). In that plan, a protocol is provided to mitigate the risks of the algorithm changes leading to changes in the device's technical specifications or negatively affecting performance specifications directly associated with the indications for use of the device. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software.

No algorithm improvements have made since the previous submission (K252103) and no changes to the PCCP were made as part of this submission

Modification	Status	Review as part of
Vertebra Algorithm: Initial	Released	K234009
Sacrum Algorithm	Released	K252103
Hip Bone Algorithm	Not released	N/A
Vertebra Algorithm: Add T13 & L6 Levels	Not released	N/A
Vertebra Algorithm: Add Cervical Levels	Not released	N/A

Conclusion

The Acorn 3D Software's Correction module possesses the same intended use and technological characteristics as the predicate device. Therefore, the Acorn 3D Correction module is substantially equivalent for its intended use.