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

December 2, 2025

Re: K252103
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: October 30, 2025
Received: October 30, 2025

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.

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.

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, Ph.D.
Assistant Director
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.	K252103

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, treatment planning, 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 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.

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).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY

Acorn 3D Alignment & Measurement

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: 29OCT2025

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
Primary Predicate Device			
K234009	QIH, LLZ	Acorn 3D Software & 3DP Model	Mighty Oak Medical
Subsequent Predicate Device			
K240582	QIH, LLZ	VEA Align; spineEOS	EOS Imaging

Introduction

This 510(k) filing seeks to expand the indications for use of the previously cleared Acorn 3D Software (K234009) to include registration capabilities and measurement functionality based on anatomical reference geometry. This submission includes the Acorn 3D Alignment & Measurement 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 Alignment & Measurement 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 Alignment & Measurement module allows the user to align anatomical structures between datasets, perform spinopelvic measurements on 3D models of anatomy, and plan 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

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.

Indications for Use

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 image segmentation system for the transfer of CT 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.

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 accuracy of alignments and measurements completed within the subject device, Acorn 3D Alignment & Measurement module, was assessed via bench testing. Accuracy of anatomical structure alignment and resulting spinopelvic measurements were evaluated both qualitatively and quantitatively. Quantitative measurement results demonstrate registration accuracy equivalent to the predicate device.

Quantitative bench testing was performed for alignment of 3D models to planar x-rays separately for two different x-ray techniques: slot beam and cone beam. For each sample (individual aligned vertebra), a Target Registration Error (TRE) was generated for a series of anatomical landmark points as the distance in mm between test alignments and ground truth. Alignment accuracy was assessed as the Median and 3rd Quartile TRE among all landmark points for each x-ray technique, as summarized below:

X-Ray Technique	Median TRE (mm)	3rd Quartile TRE (mm)
Slot Beam	1.70	2.74
Cone Beam	4.33	5.58

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 (e.g., CT and CTA)

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

Data Export

- Output information is exported in a machine-readable format (e.g., JSON and STL)

3D Models

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

Treatment Planning

- Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images

Other features

- Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm
- Pedicle Screw Placement

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

Substantial Equivalence Comparison Table

Device→ Features↓	**Acorn 3D Software** (K252103)	**Acorn 3D Software** (K234009)	**spineEOS / VEA Align** (K240582)
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)	VEA Align; spineEOS
Common Name	Image processing system	Image processing system	Automated Radiological Image Processing Software
Premarket notification	K252103	K234009	K240582
Manufacturer	Mighty Oak Medical	Mighty Oak Medical	EOS Imaging
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, treatment planning, 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 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	**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	VEA Align: This cloud-based software is intended for orthopedic applications in both pediatric and adult populations. 2D X-ray images acquired in EOS imaging's imaging systems is the foundation and resource to display the interactive landmarks overlayed on the frontal and lateral images. These landmarks are available for users to assess patient-specific global alignment. For additional assessment, alignment parameters compared to published

Device→ Features↓	**Acorn 3D Software** (K252103)	**Acorn 3D Software** (K234009)	**spineEOS / VEA Align** (K240582)
	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.** **Acorn 3D Software** and 3DP Models should be used in conjunction with expert clinical judgment.	field of musculoskeletal and craniomaxillofacial applications. **Acorn Segmentation** and 3DP Models should be used in conjunction with expert clinical judgment.	normative values may be available. This product serves as a tool to aid in the analysis of spinal deformities and degenerative diseases, and lower limb alignment disorders and deformities through precise angle and length measurements. It is suitable for use with adult and pediatric patients aged 7 years and older. Clinical judgment and experience are required to properly use the software. **spineEOS**: spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.
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 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.	spineEOS is indicated for assisting healthcare professionals with preoperative planning of spine surgeries. The product provides access to EOS images with associated 3D datasets and measurements. spineEOS includes surgical planning tools that enable users to define a patient specific surgical strategy.
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 and LLZ	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 and producing an output file	**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	VEA Align is a software indicated for assisting healthcare professionals with global alignment assessment through clinical parameters computation.

Device→ Features↓	**Acorn 3D Software** (K252103)	**Acorn 3D Software** (K234009)	**spineEOS / VEA Align** (K240582)
	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** **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.**	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 anatomy. 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.	The product uses biplanar 2D X-ray images, exclusively generated by EOS imaging's EOS (K152788) and EOSedge (K202394) systems and generates an initial placement of the patient anatomic landmarks on the images using a machine learning-based algorithm. The user may adjust the landmarks to align with the patient's anatomy. Landmark locations require user validation. The clinical parameters communicated to the user are inferred from the landmarks and are recalculated as the user adjusts the landmarks. 3D datasets may be exported for use in spineEOS for surgical planning. The product is hosted on a cloud infrastructure and relies on VEA Portal for support capabilities, such as user access control and data access. 2D X-ray image transmissions from healthcare institutions to the cloud are managed by VEA Portal. VEA Portal is a Class I 510(k)-exempt device (LMD). spineEOS is a software indicated for assisting healthcare professionals with preoperative planning of spine surgeries. EOS images (generated from EOS imaging's acquisition system) and associated 3D datasets are used as inputs of the software. The product manages clinical measurements and allows user to access surgical planning tools to define a patient specific surgical strategy. The product is indicated for adolescent and adult patients.
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 module is intended for**	**Acorn Segmentation** can be used by biomedical engineers or personnel equivalent by training or experience. Their results should be used in conjunction with expert clinical judgement.	spineEOS is a software indicated for assisting healthcare professionals with preoperative planning of spine surgeries.

Device→ Features↓	**Acorn 3D Software** (K252103)	**Acorn 3D Software** (K234009)	**spineEOS / VEA Align** (K240582)
	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:
	Acorn 3D - Segmentation
	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
	Measurement
	• Measuring on images and 3D models
	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
	Treatment Planning
	• Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images
	Other features
	Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm
	Acorn 3D – Alignment and Measurement
	Registration
		Acorn Segmentation is a standalone modular software package. This **module** 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
		Measurement
		• Measuring on images and 3D models
		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
		Treatment Planning
		• Importing of third-party STLs to visualize planned interactions with anatomy as represented in DICOM images
		Other features
		Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm
			spineEOS / VEA Align includes the following functionality:
			Image Import
			• Import of medical data
			Visualization
			• Display of data
			• Switching of view orientation
			• Basic manipulation (zoom, panning, annotations)
			Measurement
			• Distance and angle measurements on 2D images and 3D models
			• Clinical Parameters:
			  • Pelvic Tilt (PT)
			  • Sacral Slope (SS)
			  • Pelvic Incidence (PI)
			  • Pelvic Obliquity (PO)
			  • Sagittal Vertical Axis (SVA)
			  • C7-CSL
			  • PI-LL
			  • T1 Pelvic Angle (TPA)
			  • Cobb Angle
			  • Kyphosis/Lordosis Angle
			  • Knee Flexion/Extension Angle
			  • Lordosis Percentage Distributions
			  • Spondylolisthesis grade (i.e., Slippage percentage)
			Registration
			• Initial placement of anatomic landmarks on images using a machine-learning-based algorithm
			• 3D reconstruction model initialized by AI algorithm
			• Manual deformation of resulting 3D model through control points

Device→ Features↓	**Acorn 3D Software** (K252103)	**Acorn 3D Software** (K234009)	**spineEOS / VEA Align** (K240582)
	• **Alignment of anatomical structures between datasets** **Measurement** • **Standard and generic 3D measurements of spinopelvic anatomy based on user-defined reference geometry**		• Verification of deformation result by matching accurately the X-ray contours Data Export • Export of medical data
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.	N/A
Machine-Learning Models	**Acorn 3D – Segmentation** • Vertebral model (T1-T12, L1-L5) • **Sacral model**	Acorn Segmentation • Vertebral model (T1-T12, L1-L5)	N/A
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 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.	N/A

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 – no changes made to the PCCP as part of K252103). 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. Changes made under this PCCP are detailed in the table below. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software.

Modification	Rationale
Additional implementation of Sacral model	The sacrum is important to the spinopelvic pre-surgical planning workflow; auto-segmentation of the sacrum is intended to increase the speed and accuracy of the software.

Machine-Learning Model Performance Testing

Acorn 3D utilizes a machine learning algorithm to assist in the segmentation of regions of interest, with a primary focus on segmenting vertebrae from the spine in DICOM images. The algorithm produces segmentations using a convolutional neural network called U-Net, which is trained on qualified ground truth data. The software contains two models: a vertebral model, trained on vertebral levels T1-T12 and L1-L5, and a sacral model, trained on the sacrum alone.

Quantitative accuracy testing of machine-learning models was performed by direct comparison of model outputs with corresponding ground-truth segmentations by DICE similarity coefficient (DSC), a well-established metric for measuring the spatial overlap of two objects.

Model	Testing Dataset	Cases	N (Lumbar / Thoracic)	Adult / Peds	M / F	Acceptance Criteria (Threshold DSC)	Mean DSC
Vertebral (T1-T12, L1-L5)	In-House (Mighty Oak Medical)	35	450 (139 / 311)	15 / 20	12 / 23	> 0.88375	0.9331
	VERSE '20	36	401 (144 / 257)	36 / 0	22 / 14		0.94451
Sacral	In-House (Mighty Oak Medical)	40	40 (N/A)	20 / 20	13 / 27	> 0.96045	0.96630

Machine-Learning Testing Data Image Acquisition

The equipment and protocol to collect images for the Mighty Oak Medical Database are as follows:

1. Scan Type: Helical/Spiral
2. Slice Thickness: Do not exceed 1.25 mm
3. Slice Spacing: Do not exceed Slice Thickness
4. DFOV: Do not exceed 500 mm
5. Scan Matrix: 512x512

The equipment and protocol for publicly-available VERSE '20 dataset are as follows:

Inclusion criteria:

1. Patients > 30 years of age
2. No history of bone metastases

CT scanners:

1. Philips Brilliance 64 iCT 256 and IQon
2. Philips Medical Care
3. Siemens Somatom Definition AS and AS+
4. Siemens Healthineers

Imaging parameters:

1. Scan Type: Helical/Spiral
2. Peak Tube Voltage: 120 kVP
3. Slice Thickness: 0.9 – 1.0 mm

4. Tube Load: Adaptive

Machine-Learning Clinical Subgroups and Confounders

The dataset is anonymized, so available patient demographics are limited to age and gender, which were adequately represented by the data. Major factors that could confound algorithm performance include morphology (abnormal anatomy), bone quality and density, imaging quality, and the presence of orthopedic hardware. To address these, cases were limited to those that met the imaging criteria given above, and cases with hardware in the region of interest and abnormal anatomies were excluded from testing. Testing included clinical subgroups such as degenerative spinal disease, scoliosis, and DiGeorge syndrome.

Machine-Learning Ground Truth and Data Independence

Both in-house (Mighty Oak Medical) and publicly-available (VERSE '20, CTPelvic1K) datasets are produced by highly-trained experts and verified by feedback loops of expert review and manual editing and correction. Mighty Oak Medical segmentations are produced on clinical cases by operators who have undergone extensive classroom training and tests for efficacy, with an established track record of creating accurate segmentations in support of the FIREFLY Pedicle Screw Navigation Guide (K181399, K162419, and K143222).

The VERSE '20 and CTPelvic1K datasets are widely accepted as ground truth, with three levels of annotation and expert review (by medical and/or graduate students, radiology fellows, and finally a senior consultant), and being used in support of public machine-learning segmentation research.

To ensure the independence of the test data from the training data, the full training data was collected first and a k-fold was applied during training to randomly generate tuning data. Once the training-tuning was completed, an entirely new random dataset was selected from the Mighty Oak Medical database that excluded cases that were used for the training/tuning dataset. The VERSE '20 dataset was used exclusively for testing, and was not included in the training/tuning dataset. Conversely, the CTPelvic1K dataset was used exclusively in training and tuning, and was not used for testing. A summary breakdown of datasets used for training, tuning, and testing for each model is provided in the table below.

Model	Testing Dataset	Training	Tuning	Testing
Vertebral (T1-T12, L1-L5)	In-House (Mighty Oak Medical)	147	55	35
	VERSE '20	0	0	36
	Total	147	55	71
Sacral	In-House (Mighty Oak Medical)	104	47	40
	CTPelvic1K	100	55	0
	Total	204	102	40

Conclusion

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