November 3, 2025

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

Re: K251532
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: LLZ, QIH
Dated: October 6, 2025
Received: October 6, 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, PhD
Assistant Director
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.	K251532

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 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.

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

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

510(K) SUMMARY

Acorn 3D Trajectory Automation

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: 03OCT2025

Device

Trade Name: Acorn 3D Software

Common Name: Image processing system

Device Classification: Class II

Regulation, Name: 21 CFR 892.2050, Medical image management and processing system

Device Product Code: LLZ, QIH

Type of 510(k)

Original Submission: Traditional.

Predicate Device(s):

Acorn Segmentation & 3DP Model

510(k)	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K234009	LLZ, QIH	Acorn 3D Software	Mighty Oak Medical
Subsequent Predicate Device			
K141669	LLZ	Surgimap	Nemaris Inc.

Introduction

This 510(k) filing seeks to expand the indications for use of the previously cleared Acorn 3D Software (K234009) to plan pedicle screw placement in the spine. This submission includes the Acorn 3D Trajectory Automation 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 Trajectory Automation 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 Trajectory Automation module contains dedicated fully automatic algorithms for planning pedicle screw trajectories.

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
- Planning pedicle screw placement

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 Trajectory Automation 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.

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 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.

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).

Predicate Device 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 3D Trajectory Automation module and the predicate device Acorn 3D Software (K234009).

Table 1: Comparison of devices

Device→ Features↓	**Acorn 3D Software & 3DP Models** (K251532)	**Acorn 3D Software & 3DP Models** (K234009)	**Surgimap** (K141669)
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)	Surgimap
Common Name	Image processing system	Image processing system	Picture Archiving and Communication System (PACS)
Premarket notification	*K251532*	K234009	K141669
Manufacturer	Mighty Oak Medical	Mighty Oak Medical	Nemaris Inc.
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 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. **The Acorn 3D Trajectory Automation module may be used to plan pedicle screw placement in the spine in pediatric and adult patients.** **Acorn 3D Software** and 3DP Models should be used in conjunction with expert clinical judgment.	**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.	The Surgimap software assists healthcare professionals in viewing, storing, and measuring images as well as planning orthopedic surgeries. The device allows service providers to perform generic as well as specialty measurements of the images, and to plan surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants, and offer online synchronization of the database with the possibility to share data among Surgimap users. Clinical judgment and experience are required to properly use the software.

<table>
<tr><th>Device→
Features↓</th><th>Acorn 3D Software & 3DP Models
(this submission)</th><th>Acorn 3D Software & 3DP Models
(K234009)</th><th>Surgimap
(K141669)</th></tr>
<tr><td>General intended use</td><td>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.</td><td>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.</td><td>Surgimap is image analysis and surgical planning software intended for use by medical professionals to view, measure, and annotate medical images (including DICOM images) for diagnostic and preoperative planning purposes.</td></tr>
<tr><td>Product Classification</td><td>Automated radiological image processing software</td><td>Automated radiological image processing software</td><td>Medical image management and processing system.</td></tr>
<tr><td>Regulatory Class</td><td>Class II</td><td>Class II</td><td>Class II</td></tr>
<tr><td>Classification</td><td>892.2050</td><td>892.2050</td><td>892.2050</td></tr>
<tr><td>Product Code</td><td>QIH, LLZ</td><td>QIH, LLZ</td><td>LLZ</td></tr>
<tr><td>Device Description</td><td>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
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• Exporting 3D models to third-party packages
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<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></table></td><td>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
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Surgimap provides tools for orthopedic surgical planning such as templating and measuring angles, lengths, and other relevant anatomical data. The software may also be used to create preoperative plans that can be shared among healthcare professionals.

It is intended as a planning and imaging tool and not for primary image interpretation or as a sole diagnostic device.</td></tr>
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Features↓</th><th>Acorn 3D Software & 3DP Models
(this submission)</th><th>Acorn 3D Software & 3DP Models
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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 Acorn 3D Trajectory Automation 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.
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<td>Technological characteristics</td>
<td>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 (e.g. CT and CTA)
<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>Measurement</u>
• Measuring on images and 3D models
<u>Data Export</u>
• Machine-readable format (e.g. JSON and STL)
• Project Files (proprietary file format specific to the software)</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 (e.g. CT and CTA)
<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>Measurement</u>
• Measuring on images and 3D models
<u>Data Export</u>
• Machine-readable format (e.g. STL)
• Project Files (proprietary file format specific to the software)</td>
<td>Surgimap software includes the following functions:

<u>Image Import</u>
• Importing medical images in DICOM format (e.g. CT, CTA, MRI, etc.)
• Standard formats (JPEG, TIFF, PNG, PPT…)
<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>
• None
<u>Measurement</u>
• Measuring on images
<u>Data Export</u>
• Machine-readable format (e.g. CSV and DICOM)
• Project Files (proprietary file format specific to the software)</td>
</tr>
</table>

Device→ Features↓	**Acorn 3D Software & 3DP Models** (this submission)	**Acorn 3D Software & 3DP Models** (K234009)	**Surgimap** (K141669)

	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
	• **Generic Implants**
	  ○ **Pedicle Screw Implant**
	Other features
	• Using a collection of images and masks as a training dataset for machine-learning segmentation algorithm
		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
			• **Standard formats (JPG, PNG, TIFF, PDF)**
			3D Models
			• **None**
			Treatment Planning
			• **Procedures**
			  ○ **Wedge Osteotomy(ex:SPO,PSO)**
			  ○ **Opening Osteotomy**
			  ○ **Resect Osteotomy**
			  ○ **Un-Slip (i.e. spondylolisthesis correction)**
			  ○ **Anatomical Marker**
			• Generic Implants
			  ○ Screw Implant
			  ○ **Reference Line for Screw**
			  ○ **Interbody Spacer o Freehand Rod**
			  ○ **SA Rod**
			  ○ **Coronal Free hand**
			• **Vendor Specific Implant**
			  ○ **Globus Medical Spacer Template**
			  ○ **Globus Rod**
			  ○ **K2M Interbody Spacer Template**
			  ○ **K2M BACS Patient Specific Rod**
			  ○ **K2M Pre-Bent Rod Template**
			  ○ **K2M Screw**
			Other features
			• **Various**

Pedicle Screw Planning	• Surgeon Inputs / Preferences
	  ○ Screw Size
	  ○ Trajectory Angle
	  ○ **Tulip Position**
	  ○ **Breach Criteria**
	• **Automatic Optimization**
	• Review against patient imaging
		N/A	• Surgeon Inputs / Preferences
			  ○ Screw Size
			  ○ Trajectory Angle
			  ○ **Entry and End Point**
			• **Manual Optimization**
			• Review against patient imaging

Physical Model	The Acorn **3D** Segmentation **module** 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 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 in the field of orthopedic and musculoskeletal applications.	N/A
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 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.** Be advised that the quality of medical images determines the accuracy of the 3D model in Acorn 3D Software. Scanning protocols are left to the discretion of the user; however, we recommend that industry standards are referenced and followed. Only images obtained less than six months before should be used for planning and/or evaluating treatment options.	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. Be advised that the quality of medical images determines the accuracy of the 3D model in Acorn 3D Software. Scanning protocols are left to the discretion of the user; however, we recommend that industry standards are referenced and followed. Only images obtained less than six months before should be used for planning and/or evaluating treatment options.	**Surgimap is intended as a decision support system for persons who have received appropriate medical training, and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management**. All information derived from the software must be clinically reviewed regarding its plausibility before use in treating patients. Any derivation of the application of medical information from the program, other than the original design or intended use thereof, is not advised and considered a misuse of the software product.

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 pedicle screw geometry as well as pedicle screw trajectories created in the subject device, Acorn 3D Trajectory Automation, was assessed via bench testing. This was tested using worse-case-scenario conditions. Accuracy of the pedicle screws was compared using clinical data. Deviations were within the acceptance criteria. This shows that for planning pedicle screws and pedicle screw trajectories, Acorn 3D Trajectory Automation is substantially equivalent to the predicate device.

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

Measurement

- Measuring on images and 3D models

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
- Generic Implants
    - Pedicle Screw Implant

Other features

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

Conclusion

The Acorn 3D Software with Trajectory Automation possesses the same intended use and technological characteristics as the predicate devices. Therefore, the Acorn 3D Trajectory Automation module is substantially equivalent for its intended use.