



Food and Drug Administration
10903 New Hampshire Avenue
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HICAT GmbH
% Mr. Frederik Kunze
Head of Quality Management and Regulatory Affairs
Brunnenallee 6
Bonn, North Rhine - Westphalia 53177
GERMANY

November 16, 2015

Re: K152661
Trade/Device Name: HICAT Air
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 22, 2015
Received: September 23, 2015

Dear Mr. Kunze:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)

K152661

Device Name

Device Proprietary Name: HICAT Air

Indications for Use (Describe)

HICAT Air is a software application for:

- Aiding diagnosis in the ear-nose-throat region
- Aiding treatment planning in the ear-nose-throat region
- Aiding comparisons of different treatment options
- Aiding treatment planning for oral appliances

Type of Use (Select one or both, as applicable)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary for HICAT Air

Content and format as required by section 21 CFR 807.92

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm>)

1. SUBMITTER/510(K) HOLDER

HICAT GmbH
Brunnenallee 6
53177 Bonn
Germany

Establishment
Registration Number: HICAT GmbH is not registered yet

Telephone: +49 (228) 854697-38
Facsimile: +49 (228) 854697-99

Primary Contact: Mr. Frederik Kunze
Secondary Contact: Dr. Manfred Breuer

Date Prepared: September 14th, 2015

2. DEVICE NAME AND DEVICE CLASSIFICATION

Proprietary Name: HICAT Air
Common/Usual Name: Radiological Visualization Software for Diagnosis and Treatment Planning
Classification Name: System, Image Processing, Radiological
Regulation Description: Picture archiving and communications system
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Classification Class: Class II Product

3. PREDICATE DEVICES

- Primary Predicate: SICAT Function (K133320)
- Reference predicate: Dolphin Imaging 11.5 (K110430)

4. DEVICE DESCRIPTION

HICAT Air is a pure software device.

HICAT Air is a software application for the visualization and segmentation of imaging information of the ear-nose-throat (ENT) region.

The imaging data originates from medical scanners such as CT or Cone Beam – CT (CBCT) scanners.

This information can be complemented by the imaging information from optical impression systems. The additional information about the exact geometry of the tooth surfaces can be visualized together with the radiological data.

HICAT Air is also used as a software system to aid qualified medical professionals with the diagnosis, and followed by the evaluation, comparison and planning of ENT treatment options.

The medical professionals' input information and planning data may be exported from HICAT Air to be used as input data for CAD or Rapid Prototyping Systems for the manufacturing of therapeutic devices such as oral devices.

5. Indications for Use

HICAT Air is a software application for:

- Aiding diagnosis in the ear-nose-throat region
- Aiding treatment planning in the ear-nose-throat region
- Aiding comparisons of different treatment options
- Aiding treatment planning for oral appliances

6. Device Comparison Table

The following table shows a summary of the indications for use, technological characteristics, design and function of HICAT Air and the predicate devices.

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
Common / Usual Name			
	Radiological Visualization Software for Diagnosis and Treatment Planning	Not available	Radiological Visualization Software for Diagnosis and Dental Treatment Planning
Device Description			
	HICAT Air is a pure software device. HICAT Air is a software application for the visualization and segmentation of imaging information of the ear-nose-throat (ENT) region. The imaging data originates from medical scanners such as CT or Cone Beam – CT (CBCT) scanners. This information can be complemented by the imaging information from optical impression systems. The additional information about the exact geometry of	Dolphin Imaging is a pure software device. Dolphin Imaging is a software application for the visualization of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or DVT scanners. Dolphin Imaging software is designed for capturing, storing and presenting patient images and assisting in treatment planning and case	SICAT Function is a pure software device. SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or Cone Beam - CT scanners. This information can be complemented by the imaging information from optical impression systems and jaw tracking devices. The additional information about

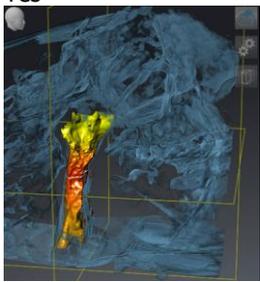
	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
	<p>the tooth surfaces can be visualized together with the radiological data.</p> <p>HICAT Air is also used as a software system to aid qualified medical professionals with the diagnosis, and followed by the evaluation, comparison and planning of ENT treatment options.</p> <p>The medical professionals' input information and planning data may be exported from HICAT Air to be used as input data for CAD or Rapid Prototyping Systems for the manufacturing of therapeutic devices such as oral devices.</p>	<p>diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.</p> <p>Acquisition of 2D image data can be performed from multiple types of devices, including digital radiography devices such as x-ray machines, generic imaging devices that support the TWAIN interface standard, such as flatbed scanners and standard image file formats (Jpeg, Bitmap, etc.) stored on a computer, camera memory card or similar.</p> <p>The following features are available:</p> <p>Import from a variety of 3D dataset formats (DICOM)</p> <p>High-quality, fast 3D rendering</p> <p>Three-dimensional airway segmentation and analysis in the ear-nose throat-region</p> <p>Airway analysis: Analyze the airway by drawing a border around your selected portion of the volumetric scan; the program will automatically fill in and display all the airway space within that border, then report back telling you the volume of airway space in cubic millimeters. It will also locate, display and measure, in square millimeters, the most constricted spot of that airway.</p> <p>Cross sections in Multiple</p>	<p>the exact geometry of the tooth surfaces and the mandibular movement can be visualized together with the radiological data.</p> <p>SICAT Function is also used as a software system to aid qualified dental professionals with the evaluation and planning of dental treatment options.</p> <p>The dental professionals' treatment planning information may be exported from SICAT Function to be used as input data for CAD or Rapid Prototyping Systems for the manufacturing of therapeutic devices such as oral appliances.</p>

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
		<p>Planar View (MPV) Precise volume orientation</p> <p>Volume stitching: Combine two separate volumes into one 2D facial photo wrap onto volume</p> <p>Volume-to-volume superimposition</p> <p>3D nerve marking</p> <p>TMJ analysis</p> <p>Generate cephalometric and panoramic radiographs</p> <p>3D-2D measurements: distance, angle and area</p> <p>Create animated movies with automated scripts</p> <p>Design image layouts and reports</p> <p>Images export to other applications</p> <p>3D implant treatment planning and simulation</p> <p>Distinguish biological structures via their radiolucency with a Hounsfield Unit measuring tool</p>	
Indications for Use			
Indications for Use	<p>HICAT Air is a software application for:</p> <ul style="list-style-type: none"> • Aiding diagnosis in the ear-nose-throat region. • Aiding treatment planning in the ear-nose-throat region. • Aiding comparisons of different treatment options. • Aiding treatment planning for oral appliances 	<p>Intended Use Statement of 510(k) Summary K110430: "Dolphin Imaging software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained</p>	<p>Indications for Use Statement of 510(k) Summary K133320: SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid qualified dental professionals with the</p>

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
		and licensed practitioners.” Product information from Appendix B-2 indicates among others: <ul style="list-style-type: none"> • Aiding diagnosis in the ENT-region • Aiding treatment planning in the ENT-region • Aiding comparisons of different treatment options 	evaluation of dental treatment options. The dental professionals' planning data may be exported from SICAT Function and used as input data for CAD or Rapid Prototyping Systems.
Contraindications	none	unknown	none
Medical Data Viewing			
Data types visualized	3D volume data, optical impressions	3D volume data, 2D radiological x-ray data, images and photographs	3D volume data, optical impressions, jaw motion tracking data
Imaging data visualization region	ENT region including the oral-maxillofacial region	ENT region including the oral-maxillofacial region	oral-maxillofacial region
Viewing Modes			
Orthogonal slices	Axial, coronal, sagittal Features and algorithms are identical to SICAT Function.	Axial, coronal, sagittal	Axial, coronal, sagittal
Special Dental View: Panoramic View	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted. (available in the optical impression registration window) Features and Algorithms are identical to SICAT Function.	Yes	Panoramic view (ray sum) based on a panoramic curve. Panoramic curve can be manually adjusted.
Special dental view: Cephalometric View	No	Yes	No
Special dental views: TSA and LSA	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve. (available in the optical impression registration window) Features and Algorithms identical to SICAT Function	Single transversal slices are generated.	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve.
3D volume rendering	Yes, volume rendering using a standard and well established ray-casting algorithm with integration along rays, and volume rendering utilizing standard	Yes	Yes

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
	shader based slicing algorithms available on typical consumer graphics hardware.		
3D surface rendering of volume data	Yes, using a standard and well established front-to-back ray-casting algorithm with an iso-surface threshold.	Yes	No
Volume Data Navigation and Manipulation			
View manipulating tools	Zoom, Pan, Change of orientation Features and Algorithms identical to SICAT Function	Yes	Zoom, Pan, Change of orientation
Color manipulating tools	Brightness, Contrast Features and Algorithms identical to SICAT Function	Yes	Brightness, Contrast
Scrolling through slices	For all slices Features and Algorithms identical to SICAT Function	Yes	For all slices (including panoramic slicing window)
3D volume clipping	Yes Features and Algorithms identical to SICAT Function	Yes	Yes
Measurements			
Length measurement	Yes Features and Algorithms identical to SICAT Function	Yes	Yes
Area measurement	Yes	Yes	No
Angle measurement	Yes Features and Algorithms identical to SICAT Function	Yes	Yes
Overall Length Measurement Accuracy	100 μm Algorithms identical to SICAT Function	unknown	100 μm
Overall Angular Measurement Accuracy	1 degree Algorithms identical to SICAT Function	unknown	1 degree
Segmentation of Anatomical Structures			
Segmentation of anatomical structures	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm, which is identical to SICAT Function)	Yes Segmentation algorithm is unknown.	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)
Airway Segmentation	Airway Segmentation of the Airway using the segmentation wizard.	Yes Segmentation algorithm is unknown.	No
Segmentation of mandible and fossa	No	No	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
Mesh texturing of the segmented airway	The Airway is texturized by a standard algorithm.	Yes	No
Optical Impression Data Visualization			
Optical impression (maxilla, mandible, or a part thereof)	Optical impression (maxilla, mandible, or a part thereof) Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in slice view Features and Algorithms identical to SICAT Function.	No	Optical impression (maxilla, mandible, or a part thereof) Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in slice view
Optical impression name	A list view in a dedicated toolbar contains the names of all loaded optical impressions. Features and Algorithms identical to SICAT Function.	No	A list view in a dedicated toolbar contains the names of all loaded optical impressions.
Show/Hide an optical impression	Yes Visibility applies to all views simultaneously. Algorithms identical to SICAT Function.	No	Yes Visibility applies to all views simultaneously.
Optical Impression Data Manipulation			
Registration of surface data (from optical impressions) to volume data	Semi-automatic, using user specified reference points. Features and Algorithms identical to SICAT Function.	No	Semi-automatic, using user specified reference points.
Fine tuning the accuracy of the registration	Restart of the registration with a different set of reference points. Features and Algorithms identical to SICAT Function.	No	Restart of the registration with a different set of reference points.
Delete	Yes Features and Algorithms identical to SICAT Function.	No	Yes
I/O			
Volume data import	DICOM	DICOM	DICOM
Optical surface data / optical impression import	Standard STL format and proprietary SSI or SIXD container format. Features and Algorithms identical to SICAT Function.	No	Standard STL format and proprietary SSI or SIXD container format.
Data Import/Export Data Compression	A "study" consisting of planning data (including segmentation information), volume data, optical surface data may be exported and imported in a SICAT proprietary format. Lossless ZIP compression	No	A "study" consisting of planning data (including segmentation information), volume data, jaw motion data and optical surface data may be exported and imported in a SICAT proprietary format.

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
	Features and Algorithms identical to SICAT Function.		Lossless ZIP compression
Export of data for CAD and rapid proto-typing	Yes	No	Yes
Misc. functions			
Soft tissue simulation with photo mapping	No	Yes	No
Cross sections in Multiple Planar View (MPV)	No	Yes	No
Volume stitching: Combine two separate volumes into one	No	Yes	No
2D facial photo wrap onto volume	No	Yes	No
Volume-to-volume superimposition	No	Yes	No
3D nerve marking	No	Yes	No
Generate panoramic radiographs	Yes	Yes	Yes
Generate cephalometric radiographs	No	Yes	No
Create animated movies with automated scripts	No	Yes	No
Design and print handout reports	Yes	Yes	No
Image export to other applications	Yes	Yes	Yes
Main Functions			
Three-dimensional airway segmentation and analysis in the ear-nose throat-region	Yes 	Yes Display of airway volume and most constricted area 	No
Airway Visualization	3D surface rendering	3D surface rendering	No
Airway Analysis: Calculation of	Yes	Yes	No

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
airway volume			
Airway Analysis: Calculation of the airway cross section dimensions	Yes	Yes	No
Airway Analysis: Calculation of the position and size of the area with minimum cross section in airway	Yes	Yes	No
Simulation of orthodontic procedures, osteotomies and distractions	No	Yes	No
Cephalometric analysis	No	Yes	No
TMJ analysis	No	Yes	Yes
3D implant treatment planning and simulation	No	Yes	No
Programming Language			
	C# and C++	Unknown	C# and C++
System Requirements			
PC Hardware Requirements (Minimum)	CPU: 2,0 GHz Dualcore RAM: 4 GB HDD: 5 GB free space Video card: Dedicated, DirectX 10 or higher 512 MB video memory Shader Model 3 "INTZ"-Surfaces Current driver Monitor: 1280x1024 pixel resolution Network: Ethernet, 100 Mbits/s Printer for patient consultation: 300 dpi; paper sizes DIN A4 or US Letter	Minimum Imaging Requirements (Rev 05/15) CPU: Intel® Core 2 RAM: 2 GB (4 GB for Dolphin 3D) HDD: 20 GB free space Video card: resolution 1024 x768 at 24-bit color Monitor: 17" Network: none Printer: 720 dpi color inkjet Camera: 3 mega pixel with camera card reader	CPU: 1 GHz RAM: 1 GB HDD: 5 GB free space Video card: Dedicated, 128 MB video memory Shader Model 3 "INTZ"-Surfaces Current driver Monitor: 1280 x 1024 pixels resolution Network: Ethernet, 100 Mbit/s Input devices: Keyboard, mouse

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
	Input devices: keyboard, mouse	Internet Broadband connection Virus protection coverage DVD-Rom drive required Scanner: 150dpi for x-rays, 300dpi for photos	
PC Software Requirements (Minimum)	Operating system: Windows 7 (32 bit or 64 bit) Windows 8 (64 bit) Windows 8.1 (64 bit) Web browser: Microsoft Internet Explorer 9 or higher Mozilla Firefox 10 or higher Google Chrome 10 or higher Apple Safari 5 or higher JavaScript has to be activated PDF viewer: with support for PDF standard 1.7, for example Adobe Reader 8 or higher	Operating system: Windows Vista or higher Word processor: MS-Word 2003 or higher	Operating system: Windows XP (32 bit) with SP3 Windows Vista (32 bit or 64 bit) Windows 7 (32 bit or 64 bit) Windows 8 (32 bit or 64-bit)
Compliance to Standards and Guidance			
	<ul style="list-style-type: none"> •NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. •ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices. •IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes. • AAMI/ANSI/IEC 62366:2007/(R)2013, Medical devices - Application of usability engineering to medical devices •SMPTE Recommended Practice RP 133-1991: Specifications for Medical 	unknown	<ul style="list-style-type: none"> •NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. •ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices. •IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes. •ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(r)2012 and A2:2010/(r)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential

	HICAT Air Proposed	Reference predicate Dolphin Imaging 11.5 (K110430)	Primary predicate SICAT Function (K133320)
	<p>Diagnostic Imaging Test Pattern for Television Monitors and Hard-copy Recording Cameras</p> <ul style="list-style-type: none"> • HIPAA 45 CFR Part 160 – General Administrative Requirements • HIPAA 45 CFR Part 164 – Security and Privacy • Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, Document issued on: July 27, 2000 • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005 • Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, Document issued on: September 9, 1999 • Device Labeling Guidance, March 8, 1991 (G91-1) • General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002 • Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005 • Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: July 18, 2000 		<p>performance (IEC 60601-1:2005, MOD).</p> <ul style="list-style-type: none"> • IEC 62366:2007, Medical devices - Application of usability engineering to medical devices • SMPTE Recommended Practice RP 133-1991: Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-copy Recording Cameras • HIPAA 45 CFR Part 160 – General Administrative Requirements • HIPAA 45 CFR Part 164 – Security and Privacy • Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, Document issued on: July 27, 2000 • Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005 • Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, Document issued on: September 9, 1999 • Device Labeling Guidance, March 8, 1991 (G91-1) • General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002 • Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005 • Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: July 18, 2000

Missing features of HICAT Air compared to the predicate devices are connected to the simulation of orthodontic procedures, osteotomies and distractions, to cephalometric

analysis, to TMJ analysis and to implant treatment planning and simulation. This does not have an impact on the safety and effectiveness of HICAT Air concerning the visualization and segmentation of imaging information and the evaluation of treatment options.

HICAT Air and the two predicate devices, SICAT Function and Dolphin Imaging 11.5, are software devices for visualization and segmentation of imaging information. Additional features of HICAT Air compared to the predicate device SICAT Function is the analysis in the ear-nose-throat region, particularly the airway analysis, including the three-dimensional airway segmentation and visualization. However the software algorithms used in HICAT Air are identical to the predicate device SICAT Function. Performance testing has been used to validate the safety and effectiveness of the HICAT Air segmentation features in comparison to the predicate device Dolphin Imaging 11.5.

7. Non-Clinical Performance Testing and Verification and Validation Activities

For HICAT Air, software verification and validation activities were performed, in accordance with the following Guidances and Standards:

- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set.
- ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices.
- IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes.
- IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- SMPTE Recommended Practice RP 133-1991: Specifications for Medical Diagnostic Imaging Test Pattern for Television Monitors and Hard-copy Recording Cameras
- HIPAA 45 CFR Part 160 – General Administrative Requirements
- HIPAA 45 CFR Part 164 – Security and Privacy
- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, Document issued on: July 27, 2000
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Document issued on: May 11, 2005
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, Document issued on: September 9, 1999
- Device Labeling Guidance, March 8, 1991 (G91-1)
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002
- Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, Document issued on: January 14, 2005

- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: July 18, 2000

Among others the following verification and validation activities were performed:

- Design Validation/Reviews
- Unit Tests
- Code Reviews
- Usability Tests
- Integration Tests
- System Verification Tests
- System Validation Tests

Special bench testing has been performed with non-clinical data:

- to verify the segmentation performance of anatomical structures of the airway using a segmentation wizard and
- to verify the correct calculation of geometric dimensions of the airway by the airway analysis tool.

Test reports for integration testing, system verification and validation testing and bench testing are included with this premarket notification.

A verification and validation activities summary report provided with this premarket notification concludes that HICAT Air passed all verification and validation activities and that safety and effectiveness of the product has been demonstrated in the context of its indications for use.

8. Conclusion

Based on the information and supporting documentation provided in this premarket notification, HICAT Air is considered to be substantially equivalent in design, material and function to the predicate devices. It is believed to perform as well as the predicate devices for the visualization and segmentation of imaging information and the evaluation of treatment options. Any minor differences between HICAT Air and the predicate devices do not effect safety and performance.