de Götzen S.r.l
℅ Dario Bandiera
Quality Manager
via Roma, 45
Olgiate, Olona 21057
ITALY

February 11, 2020

Re: K192165
Trade/Device Name: Acteon Imaging Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 2, 2019
Received: January 13, 2020

Dear Dario Bandiera:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192165

Device Name
Acteon Imaging Suite

Indications for Use *(Describe)*
Acteon Imaging Suite software program is indicated for general dental and maxillofacial diagnostic imaging. It controls exam retrieval, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

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.

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The summary of this 510(k) is submitted in accordance with the requirements of 21 CFR Part 807.92.

SUBMITTER

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Contact Person:	Dario Bandiera – dario.bandiera@acteongroup.com
Date:	September 24th,2019

Table 1: Submitter

DEVICE

Name of the device:	Acteon Imaging Suite
Common or Usual name:	Imaging application software
Classification name:	Picture Archiving and Communication System (21 CFR 892.2050)
Regulatory class:	II
Product Code:	LLZ

Table 2: device

PRIMARY PREDICATE DEVICE

Legally marketed device to which equivalence is claimed is:

PRIMARY PREDICATE DEVICE	
Device name	Cliniview
Manufacturer	Palodex Group Oy
Device product code	LLZ
Regulation number	21 CFR 892.2050
Regulation name	Picture Archiving and Communication System
Clearance date	April, 25 2017
510(k) number	K162799

Table 3: primary predicate device

This predicate has not been subjected to a design-related recall.

SECONDARY PREDICATE DEVICE

Legally marketed device to which equivalence is claimed is:

SECONDARY PREDICATE DEVICE	
Device name	Planmeca Romexis
Manufacturer	Planmeca Oy
Device product code	LLZ
Regulation number	21 CFR 892.2050
Regulation name	Picture Archiving and Communication System
Clearance date	November, 14 2017
510(k) number	K171385

Table 4: secondary predicate device

This predicate has not been subjected to a design-related recall.

No reference devices were used in this submission.

DEVICE DESCRIPTION

AIS–Acteon Imaging Suite is an application software suite providing a set of tools used to meet the imaging requirements set by different types of dental facilities – from small clinics to large hospitals. It enables practitioners to process and permanently archive (in connection with patients) diagnostic images relating to intraoral, maxillofacial and ear nose throat areas. Images can be originated by: intraoral digital sensors, dental panoramic and cephalometric equipment, CBCT equipment, intraoral cameras and all the future ACTEON digital imaging devices. The devices that are intended to be used with AIS are X-MIND trium, X-MIND PRIME and Cameras, Sopix², Sopix² ACE, PSPix, PSPix², SOPROCare camera and SOPROLife (with SDK provided by ACTEON-SOPRO). AIS supports DICOM format, which makes the system flexible and ready to be connected to other compatible devices and applications.

Here below a scheme showing the main components of the device under analysis:

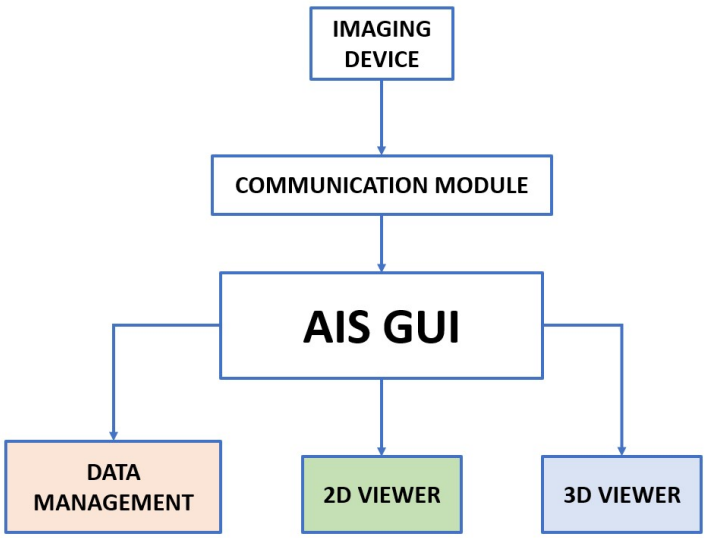


Figure 1: main components

The acquisition device communicates and transfer data to AIS through dedicated communication modules. These modules are specifically designed or rely completely on well-known and established Twain communication protocol.
AIS GUI consists of the following main parts:

- Patient selection window

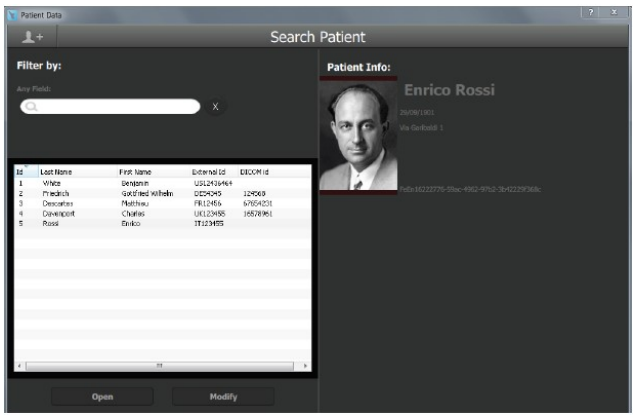


Figure 2: Patient selection window

Patient selection window allows the user to search the patient folder and open related clinic view that contains all diagnostic acquired or imported images, report and so on.

- Clinic view

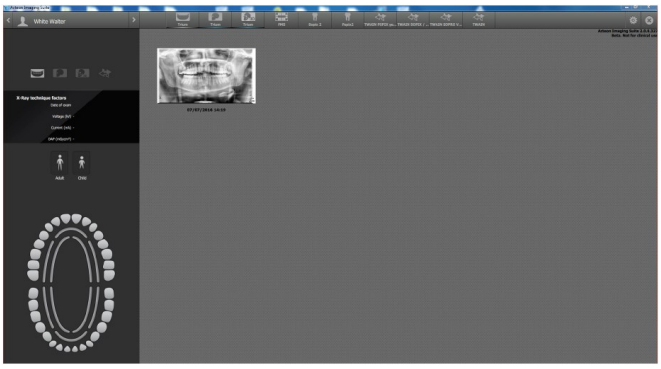


Figure 3: Clinic view

Clinic view allows to show all diagnostic images acquired or imported, report It is possible to filter the exam by date, exam type or by dental chart. Clinic view is the starting point to perform a new exam. It's also possible to open 3D viewer tool for 3D datasets or 2D viewer tool for 2D acquisitions.

- 2D App

Figure 4: 2D App

2D App is the tool to view 2D images. In that tool it is possible to adjust image, gamma, contrast, luminosity and sharpness. 2D App provides also tools to annotate the image.

- 3D App

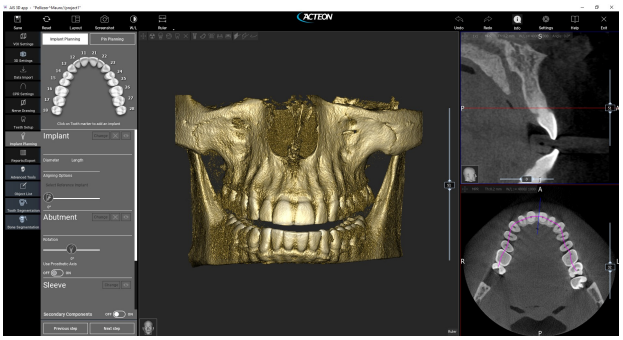


Figure 5: 3D APP

3D App is the tool to view 3D volumes and plan implants. It is cleared under K173041 3DIEMME Ltd.

- AIS Report Module

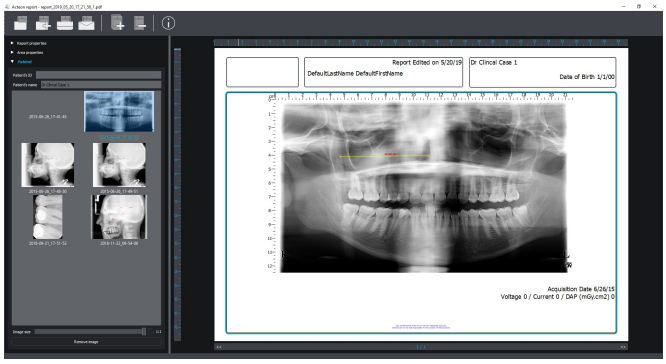


Figure 6: AIS report module

Report module provides the functionalities to allow the user to create customized reports, generating Portable Data Format (PDF) documents or printing directly on standard printers.

- AIS Configurator

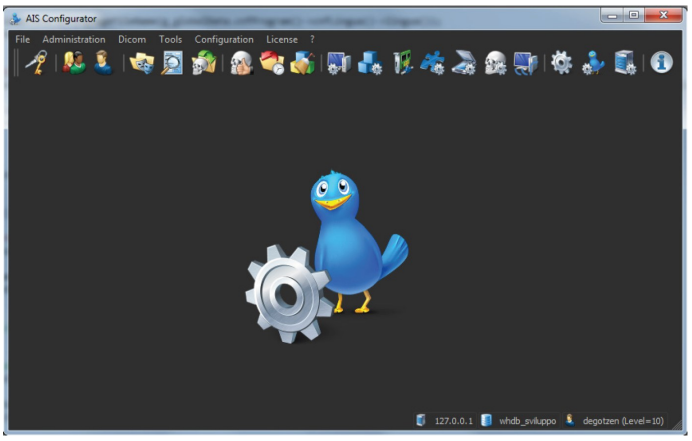


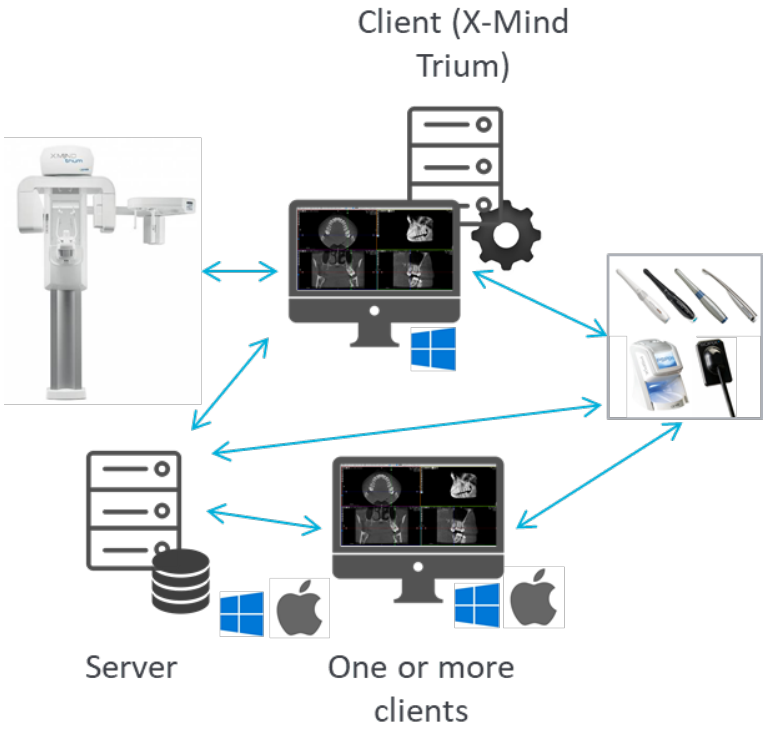
Figure 7: AIS configurator

This application is needed to manage database, change AIS general settings and set up PMS communication.
The data management component is needed to store patient data and images into AIS database and to manage them.
2D and 3D viewer are the tools required for data representation, both implement also image processing and measuring features.

I. Network functionalities

Acteon Imaging Suite has the possibility to be deployed in a Local Area Network (LAN) in a Client-Server architecture:

- Clients are dedicated to exam retrieval, display and enhancement;
- Server is dedicated to store patient data and images, it provides also all the functionalities available on the client.



Communication between server and client is made in TCP/IP.

II. Data Storage

Exam data are stored on server Hard Drive Disk (HDD) or Solid Stated Drive (SSD) in anonymized image files.
Patient data are stored in crypted database to ensure privacy, the database file data are usually installed in the same drive of the exam data.

Acteon Imaging Suite provides the user with facilities for backup the data to prevent disk failure.

III. Exam format

Exam are saved both in Acteon proprietary format (DGI) as RAW or in standard format (TIF, JPG, PNG or DICOM).
The proprietary format (DGI) is used to give the user the possibility to apply different filters,

IV. Hardware

Acteon Imaging Suite can be installed on every hardware compliant with the minimum requirements. No hardware is provided with the software.
Hardware, with Acteon Imaging Suite installed, can be provided by de Götzen S.r.l. – ACTEON Group with other Acteon Devices, for example X-MIND trium.

INDICATIONS FOR USE

Acteon Imaging Suite software program is indicated for general dental and maxillofacial diagnostic imaging. It controls exam retrieval, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table here below contains a comparison of the technological characteristics

Feature	Proposed	Predicate 1	Predicate 2
	Acteon Imaging Suite (AIS)	Cliniview	Romexis
Manufacturer	de Götzen S.r.l. – ACTEON Group	KaVo	Planmeca
510 (k) number	To be obtained	K162799	K171385
Indication for use / intended use	Acteon Imaging Suite software program is indicated for general dental and maxillofacial diagnostic imaging. It controls exam retrieval, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.	Cliniview software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from digital various imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.	Planmeca Romexis is a medical imaging software, and is intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended to retrieve, process, render, diagnose, review, store, print, and distribute images.

Feature	Proposed	Predicate 1	Predicate 2
	Acteon Imaging Suite (AIS)	Cliniview	Romexis
Implementation	Software Only	Software Only	Software Only
Host processor speed	Intel Core i5 or better	Intel Core i3 or better	Processing Intel Core 2 Duo 2 GHz or better
Host Monitor size	Full HD	19" or larger recommended	Full HD
Display resolution	1600x1024	1280x1024 resolution 24-bit color Monitor must provide a brightness of 300cd/m2 for rooms <1000 lux and a minimum contrast ratio of 100:1	1280x1024 (1920x1080 recommended)
User Display Preferences	Yes	Yes	Yes
USB and S Video Support	USB support	USB and S Video support	USB Support
Receive images from other systems	Yes	Yes	Yes
Images displayed	2D and 3D dental X-rays, intraoral and extraoral images	2D dental x-rays, intraoral and extraoral images	2D and 3D dental X-rays, intraoral and extraoral images
Database	Image related data are stored in the AIS database or remotely accessible	Images and related data are stored in the Cliniview database or	Images and metadata are stored in the Romexis

Feature	Proposed	Predicate 1	Predicate 2
	Acteon Imaging Suite (AIS)	Cliniview	Romexis
	database in the network.	remotely accessible database in the network.	database.
Image acquisition	Imaging plate scanners, intraoral sensors, intraoral video camera, digital extra oral x-ray devices, various image file formats	Imaging plate scanners, intraoral sensors, intraoral video camera, digital extra oral x-ray devices, various image file formats	Imaging plate scanners, intraoral sensors, intraoral video camera, digital extra oral xray devices, various image file formats
Overall functionality	The imaging program for X-ray, color images and video cameras	The imaging program for X-ray and color images	The imaging software for digital imaging devices and video cameras
Image processing functionality	Enhancement, annotation, measurements, import/export and printing image or report files	Enhancement, annotation, measurements, import/export and printing files.	Enhancement and archiving images
Host platform	PC and Apple Mac	PC	PC and Apple Mac
Host operating system	Windows 7 Ultimate/Professional (64-bit) Windows 8 Professional (64-bit) Windows 10 64-bit	Windows 7 Professional/Ultimate/ Enterprise SP1(32/64-bit) Windows 8/8.1 Professional/ Enterprise(3/64bit)	Windows 7 Professional (32/64bit) Windows 8.1 Professional (32/64bit) Windows 10 64-

Feature	Proposed	Predicate 1	Predicate 2
	Acteon Imaging Suite (AIS)	Cliniview	Romexis
	Windows Server 2016 Mac OS X (Intel)	Windows 10 Windows Server 2012/2012R2	bit Windows Server 2008 Windows Server 2012 Mac OS X (Intel)
Host RAM	8 GB	4 GB	Workstations: 3/8 GB Servers: 3/8 GB
Host magnetic storage	1 TB	8 GB free space 10 GB hard disk database	Workstations: 80GB Servers: 2x500 GB
Host floppy drives	Not Required	Not Required	Not Required
Installation media	DVD or Network	DVD or Network	DVD ROM or R/W drive
Viewers/ modes	Intraoral, Panoramic, CEPHALOMETRIC, 2D linear tomography photos, Stack images, 3D CBCT, 3D photo, 3D surface scan	Intraoral, Panoramic, CEPHALOMETRIC, 3D CBCT, color photographs	Intraoral, Panoramic, CEPHALOMETRIC, 2D linear tomography photos,Stack images, 3D CBCT, 3D photo, 3D surface scan
Implant planning	Implant library, which can be used for implant planning, searching for	Implant library, which can be used for implant planning, searching for implants,	Optional implant library, which can be used for implant

Feature	Proposed	Predicate 1	Predicate 2
	Acteon Imaging Suite (AIS)	Cliniview	Romexis
	implants, creating new implants, modifying, adding and replacing implants in the plan	creating new implants, modifying, adding and replacing implants in the plan	planning, searching for implants, creating new implants, modifying, adding and replacing implants in the plan
Supports mobile application	No	iPad application	iPad and iPhone application

Table 5 Comparison between proposed and predicate devices.

Non clinical performance data:

The safety and effectiveness of Acteon Imaging Suite software have been evaluated via:

- Internal design verification and validation testing;
- Risk management;
- Conformance to recognized standards and guidelines;
- Cybersecurity risk management;
- Bench tests comparative on image processing.

INTERNAL DESIGN VERIFICATION AND VALIDATION TESTING

Internal design verification and validation activities have been performed according to design and development internal procedure and configuration management plan taking into account requirements of

- IEC 62304 Medical device software - Software life cycle processes ed. 1.1: 2015
- ISO 14971: Medical devices- Application of risk management to medical devices 2012
- AAMI TIR57 2016 Principles for medical device security—Risk management

and general principles of software validation included in Guidance for Industry and FDA Staff 2002

The person having the overall responsibility for this validation is independent of the design team, no member of the design team is responsible for the validation of their own design.
Protocol and acceptance criteria have been defined, revised and approved according to Software Validation Procedure that is written according to the standards above.
A specific software (TestRail) has been used to manage validation and traceability of AIS Traceability matrix and specific cybersecurity traceability matrix have been compiled

For each tested item have been defined the following aspects:
Purpose
Preconditions
Impact on safety and related control measure if any
Operative system where tested and role (client/server)
If regression test has been performed
Testing steps and related expected results.

Results of testing are reported in Software validation reports
Testing of all items that could affect safety of the device must have PASS as a result, while it is possible to release the software with minor anomalies. All the anomalies must be solved or justified before the release.

CONFORMANCE TO RECOGNIZED STANDARDS AND GUIDELINES

Acteon Imaging Suite is compliant with IEC 62304:2006/AMD1: 2015.

Software safety class is determined analyzing the harms that a software failure can cause, as described in the specific flow chart taken from IEC 62304:2006/AMD1: 2015. AIS is a Class B software following IEC 62304

therefore, all the requirements for a class B software have been satisfied.

Acteon Imaging Suite is compliant with IEC 60601-1-6; IEC 62366-1: 2013
The activities related to the usability process implementation have been conducted, following indications and rules of IEC 60601-1-6 and IEC 62366: 2015

and according to the flow chart shown in fig.8 below.

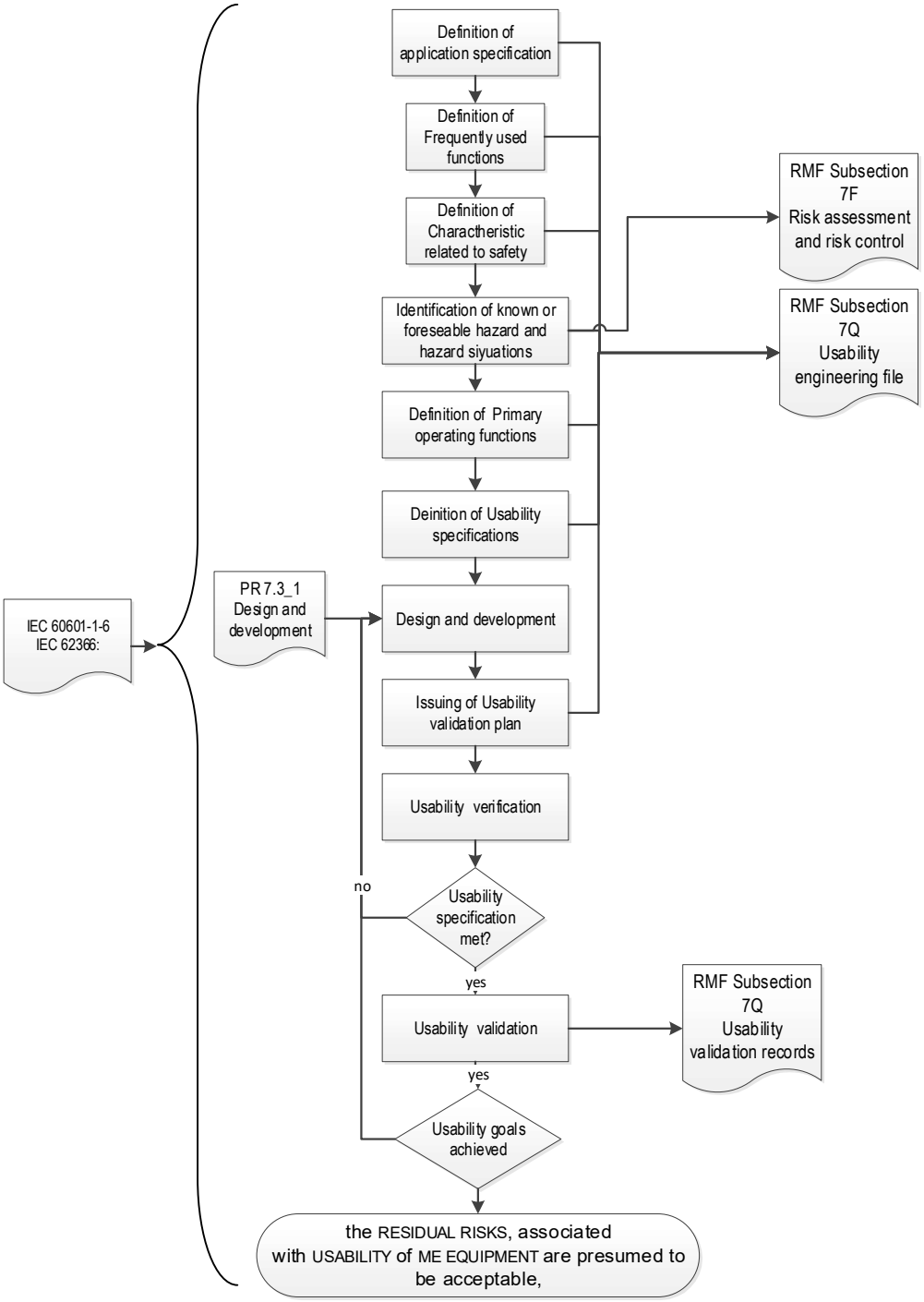


Figure 8: usability flow chart

Acteon Imaging Suite is compliant with NEMA PS 3.1 - 3.20 NEMA 12-300 Digital Imaging and Communications in Medicine (DICOM) Set

SUMMARY FOR ANY PERFORMANCE TESTING IN THE SUBMISSION

Software is verified through unit, integration, system and architecture testing.
Since the functionalities of AIS are the same of the predicate device ones and, since there are no significant technology differences, the equivalence has been demonstrated comparing the image rendering of different software with regards to the clinical effectiveness of that image.

Three independent reviewers having different backgrounds (maxillofacial surgery, orthodontics, dentistry) evaluated the same images, rendered on the same hardware (both Windows and MacOs) or printed with same printer, in order to evaluate the image quality (anatomical coverage, density and image contrast and anatomical structures) to assess suitability for clinical use.

CONCLUSIONS

Substantial equivalence:
There are no significant differences between the proposed device Acteon Imaging Suite and the predicates.
The proposed device is substantially equivalent to the predicate devices basing on:

- Indication for Use statement;
- Offered functionalities;
- Theory of operations.

All the hardware requirements of Acteon Imaging Suite are equal or more restrictive respect to the predicate devices.

The substantial equivalence has been demonstrated using bench tests that compare clinical suitability of the rendering performed by Acteon Imaging Suite with the predicates.

Acteon Imaging Suite is substantially equivalent to Cliniview software cleared under K162799 and Romexis cleared under K171385.

Minor differences in specifications do not affect safety and effectiveness of the device.