Abys Medical
Arnaud Destainville
CEO
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La Rochelle, 17000
France

December 30, 2022

Re: K221796
Trade/Device Name: Cyware 4H and Cysart 4H
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 2, 2022
Received: December 2, 2022

Dear Arnaud Destainville:

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,

Jessica Lamb, Ph. D.
Assistant Director
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221796

Device Name
Cysware 4H
Cysart 4H

Indications for Use *(Describe)*
Abys® Medical Cysware® 4H is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Abys® Medical Cysware® 4H is also intended as pre-operative software for surgical planning assistance. Abys® Medical Cysware® 4H is intended to be used by clinician with appropriate clinical judgement.

Abys® Medical Cysart® 4H is a medical display intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from CT scan source. The device is intended to provide visual information to be used by clinician with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. Abys® Medical Cysart® 4H is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. Abys® Medical Cysart® 4H is intended to be used as a reference display for consultation to assist the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.

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.

510(k) SUMMARY

ABYS MEDICAL's CYSWARE® 4H and CYSART® 4H

Date Prepared: December 29, 2022

1. Submitter

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2. Contact person

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3. Device identification

Trade/Proprietary Names: Cysware® 4H / Cysart® 4H

Common/Usual Name: Medical Image Management and Processing System

Classification Name: System, image processing, radiological

Regulation Number: 21 CFR §892.2050

Product Code: LLZ

Class: II

4. Legally Marketed Predicate Devices

Primary predicate device:

- Simpleware ScanIP Medical (Synopsys (Northern Europe) Ltd, K203195)

Additional predicate devices:

- Surgimap 2.0 (Nemaris, Inc, K141669)
- NovaPACS (Novarad Corporation, K171754)
- HOLOSCOPE-I (Real View Imaging Ltd, K210072)
- OpenSight (Novarad Corporation, K172418)

One Urgent Medical Device Correction Notice has been published on 09/24/2019 for the NovaPACS (Novarad Corporation, K171754) for the issue: "The firm received a report of an atypical dataset being generated. When using the cross-localization feature and images from a modality that generates asymmetrical images, the cross-localization reference line may be inaccurately placed on any of the corresponding images that are open." The action required a software update.

None of those devices have not been subject to a design-related recall.

5. Description of the devices

Abys® Medical Cysware® 4H web platform is a web-based medical device designed and intended for use prior to surgery to gather in one place the information needed by the surgeon to make a surgical planning. As a result, a planning assistance file is created and contains medical imaging, 3d models, documents, and notes. The ABYS® MEDICAL Cysware® 4H web platform is used to export the planning assistance file to the Abys® Medical Cysart® 4H mixed reality application, another medical software.

The Abys® Medical Cysart® 4H mixed reality application is a medical device designed and intended for use in office room and in operating room to display and manipulate all documents in the planning assistance file generated from the Abys® Medical Cysware® 4H web platform.

6. Indication for Use

Abys® Medical Cysware® 4H is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Abys® Medical Cysware® 4H is also intended as pre-operative software for surgical planning assistance. Abys® Medical Cysware® 4H is intended to be used by clinician with appropriate clinical judgement.

Abys® Medical Cysart® 4H is a medical display intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from CT scan source. The device is intended to provide visual information to be used by clinician with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. Abys® Medical Cysart® 4H is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. Abys® Medical Cysart® 4H is intended to be used as a reference display for consultation to assist the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.

7. Substantial Equivalence

The following table compares the Cysware ® 4H to the Simpleware ScanIP Medical, the Surgimap 2.0 and the NovaPACS predicate devices with respect to indications for use, features, and technological characteristics.

Devices information's	Cysware® 4H ABYS® MEDICAL (Submitted device) 21 CFR 892.2050	Simpleware ScanIP Medical Synopsys (Northern Europe) Ltd (Primary predicate) 21 CFR 892.2050	Surgimap 2.0 Nemaris, Inc (Additional predicate) 21 CFR 892.2050	NovaPACS Novarad Corporation (Additional predicate) 21 CFR 892.2050
Sponsor	ABYS® MEDICAL	Synopsys (Northern Europe) Ltd	Nemaris, Inc	Novarad Corporation
510(k) Number	Present submission	K203195	K141669	K171754
Product code	LLZ	LLZ	LLZ	LLZ
Device class	II	II	II	II
Device classification	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
Intended environment	Hospital	Hospital	Hospital	Hospital
Intended use	Intended for use to import, visualize, annotate, segment medical images	Intended for use to import, visualize, annotate, segment medical images	Intended for use to import, visualize, annotate, segment medical images	Intended for use to import, visualize, annotate, segment medical images

Indications	Abys® Medical Cysware® 4H is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Abys® Medical Cysware® 4H is also intended as pre-operative software for surgical planning assistance. Abys® Medical Cysware® 4H is intended to be used by clinician with appropriate clinical judgement.	Simpleware ScanIP Medical is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. It is also intended as pre-operative software for diagnostic and surgical planning. For these purposes, output files can also be used for the fabrication of physical replicas using traditional or additive manufacturing methods. The physical replicas can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. The software is intended to be used in conjunction with other diagnostic tools and 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.	NovaPACS is intended for the viewing, archiving, analysis, annotation, registration, distribution, editing, fusion, and processing of digital medical images and data acquired from diagnostic imaging devices and all DICOM devices, including mammography. NovaPACS is intended for use by trained healthcare professionals, including radiologists, physicians, technologists, clinicians, and nurses. NovaPACS allows the end user to display, manipulate, archive, and evaluate images. Mobile devices are not intended to replace a full workstation and should be used only when there is no access to a workstation. They are not to be used for mammography or fMRI. Mobile devices are used for diagnosis of medical images

				from different modalities. including CT, MR, US, CR/DX, NM, PT, and XA. For a list of compatible mobile platforms see NovaPACS Diagnostic Viewer User Manual. While NovaPACS full workstation provides tools to assist the healthcare professional determine diagnostic viability, it is the user's responsibility to ensure quality, display contrast, ambient light conditions, and to confirm image compression ratios are consistent with the generally accepted standards of the clinical application. NovaPACS is intended for providing analysis and visualization of functional MRI data of the human brain, presenting derived properties and parameters in a clinically useful context.

Intended users	Clinician with appropriate clinical judgement	Healthcare professionals	Healthcare professionals	Healthcare professionals, including radiologists, physicians, technologists, clinicians, and nurses
User interface	PC	PC	PC or mobile device	PC or dedicate workstation
Web-based	Yes	None	Yes	Yes
Operating system	PC: Windows	PC: Windows, + Windows server 2016	PC: Windows + MAC Mobile: Android + iOS	Not disclosed
Medical Image type	CT DICOM	CT and MRI DICOM	All DICOM	All DICOM including CT, MR, US, CR/DX, NM, PT, and XA
Other type of content	JPEG, PNG, PDF, URL	Not disclosed	Not disclosed	JPEG
Subspecialties	No restriction	No restriction	Orthopedic	No restriction
Output file	Yes	Yes	Yes	Unknown
MPR view	Yes	Yes	Yes	Yes
Provides Values for Measurement	Yes Distance and angle measurement	Yes Including distance and angle measurement	Yes Generic and specific measurement	Yes Distance measurement
Preoperative annotation and analysis	Yes	Yes	Not disclosed	Yes
Image filtering and segmentation tools	Yes	Yes	Not disclosed	Not disclosed
Obtaining images	Local transfer from the computer	Local transfer from the computer	Transferred from other devices or mobile device camera	Not disclosed

Case sharing with collaborator	Yes By granting limited access right to other health professional users of Cysware® 4H	None	Yes By granting limited access right to other health professional users of Surgimap 2.0	Yes By granting limited access right to other health professional users of NovaPACS
Restricted permission in case of case sharing	Yes View or edition permission Case sharing duration limited by an end date specified by the user	Not applicable	Yes View or edition permission	Yes Several states of case review
Access to case through 3D mixed reality application	Yes Sharing to ABYS® MEDICAL Cysart® 4H	None	None	Yes Sharing to Novarad Corporation Opensight (K172418)

Table 1 Comparison table with predicates: Cysware® 4H

The Cysware® 4H does not raise new questions of safety and effectiveness than its predicates regarding with existing methods to visualize 2D and 3D imaging of the patient, for preoperative planning of surgical options.

The following table compares the Cysart® 4H to the HOLOSCOPE-I and the OpenSight predicate devices with respect to indications for use, features, and technological characteristics.

Devices information's	Cysart® 4H ABYS® MEDICAL (Submitted device) 21 CFR 892.2050	HOLOSCOPE-i Real View Imaging Ltd (Additional predicate) 21 CFR 892.2050	OpenSight Novarad Corporation (Additional predicate) 21 CFR 892.2050
Sponsor	ABYS® MEDICAL	Real View Imaging Ltd	Novarad Corporation
510(k) Number	Present submission (K221796)	K210072	K172418
Product code	LLZ	LLZ	LLZ

Devices information's	Cysart® 4H ABYS® MEDICAL (Submitted device) 21 CFR 892.2050	HOLOSCOPE-i Real View Imaging Ltd (Additional predicate) 21 CFR 892.2050	OpenSight Novarad Corporation (Additional predicate) 21 CFR 892.2050
Device class	II	II	II
Device classification	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
Intended environment	Operating room	Operating room	Healthcare settings, such as hospitals and clinics
Intended holographic display	Microsoft® HoloLens®2	HOLOSCOPE-I workstation	Microsoft® HoloLens®
Intended use	Intended for use to display and manipulate 3D images in mixed reality	Intended for use to display and manipulate 3D images in mixed reality	Intended for use to display and manipulate 3D images in mixed reality

Indications	Abys® Medical Cysart® 4H is a medical display intended for 3D image visualization and image interaction. The stereoscopic 3D images are generated from 3D volumetric data acquired from CT scan source. The device is intended to provide visual information to be used by clinician with appropriate clinical judgement for analysis of surgical options, and the intraoperative display of the images. Abys® Medical Cysart® 4H is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. Abys® Medical Cysart® 4H is intended to be used as a reference display for consultation to assist the clinician with appropriate clinical judgement who is responsible for making all final patient management decisions.	The HOLOSCOPE-i is a medical display workstation intended for 3D image visualization and image interaction. The holograms are generated from 3D volumetric data acquired from CT and Ultrasound sources. The device is intended to provide visual information to be used by the health care professional for analysis of surgical options, and the intraoperative display of the images. The HOLOSCOPE-i is intended to be used as an adjunct to the interpretation of images performed using diagnostic imaging systems and is not intended for primary diagnosis. The HOLOSCOPE-i is intended to be used as a reference display for consultation to assist the clinician who is responsible for making all final patient management decisions.	The OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for pre-operative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation. OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the same anatomy of the patient in order to support pre-operative analysis. OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures. OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The

Devices information's	Cysart® 4H ABYS® MEDICAL (Submitted device) 21 CFR 892.2050	HOLOSCOPE-i Real View Imaging Ltd (Additional predicate) 21 CFR 892.2050	OpenSight Novarad Corporation (Additional predicate) 21 CFR 892.2050
			device assists doctors to better understand anatomy and pathology of patient.
Intended users	Clinician with appropriate clinical judgement	Health care professional for making all final patient management decisions	Trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators
Stereoscopic medical image hologram	Yes	Yes	Yes
Subspecialties	No restriction	No restriction	No restriction
Operating System	Windows Holographic Operating System	Not disclosed	Windows Holographic Operating System
Holographic device connection	Wireless	Embedded to a workstation	Wireless
Image source	CT	CT and Ultrasound	CR, DX, CT, MR, and PT
Interactive model manipulation	Hand Tracking	Remote Control Pad	Hand Tracking
Models Interactions/Edition	Interactive manipulation, zoom, rotate, move, scale	Interactive manipulation, zoom, rotate, move, slice, mark, measure	Interactive manipulation, zoom, rotate, move, slice, mark
Display settings	Brightness, image transparency	Brightness	Quality, color, window level
Image type	3D medical images, 2D documents like PDF, personal notes	3D medical images	3D medical images
Vocal control	Yes	Not disclosed	Yes
User interface	Virtual dashboard	Remote Control Pad	Virtual dashboard

Table 2 Comparison table with predicates: Cysart® 4H

The Cysart® 4H software does not raise new questions of safety and effectiveness compared to its predicates, in regards with existing methods to visualize 3D stereoscopic images of the patient, for preoperative planning of surgical options and for intraoperative use.

8. Non-Clinical Performance Data

The Cysware® 4H and Cysart® 4H software have been developed, verified, and validated in accordance with FDA guidelines, ISO 62304 "Medical Device Software – Software Life-Cycle Processes", IEC 62366-1 "Medical devices – Part 1: Application of usability engineering to medical devices" and 14971 "Application of Risk Management to Medical Devices".

The testing results support that all the specifications have met the acceptance criteria. The ABYS® MEDICAL Cysware® 4H device and the ABYS® MEDICAL Cysart® 4H device passed all the tests and support the claims of substantial equivalence and safety for their intended use. The usability assessment of the ABYS® MEDICAL Cysware® 4H and the ABYS® MEDICAL Cysart® 4H under their intended use has been carried out. This validation demonstrated the ease of use of ABYS® MEDICAL Cysware® 4H and ABYS® MEDICAL Cysart® 4H by the clinicians.

Specifics performance test campaigns were carried out for the Cysware® 4H to demonstrate that:

- The global time needed for Cysware® 4H to open a planification assistance file is below 40 seconds, with the mention that it does not include timelapse of credentials entering. Global time with credentials entering is user dependent and may reach 1-2 minutes, as showed by summative tests.
- The features are usable when fifteen users are simultaneously connected to Cysware® 4H.
- The features are usable when three users are simultaneously connected to the same folder.
- Accuracy of measures was described through trueness and showing error lower than 1.6 mm for distances and 2.9° for the angles.
- Accuracy of Cysware 4H segmentation algorithm and Mesh generation for Cysart 4H export allow to segment DICOM from CT scan source with an error lower than 1.25mm.

Specifics performance test campaigns were carried out for the Cysart® 4H to demonstrate that:

- The images displayed have a refresh rate always higher than 30 frames per second, ensuring the smooth movement of the 3D objects
- The autonomy of the HoloLens 2 when the application is open allows for the entirety of a surgery. More specifically 1h30 without sharing the video stream and 45 minutes while sharing the video stream to a workstation connected to the same network
- The Cysart® 4H device reproduces the 3D objects at a scale of 1:1 and thus ensures that the 3D medical images displayed are representative of the medical images acquired from the CT scan
- The global time to connect to a Cysart® 4H session is no longer than 3 minutes

- The quality of display is sufficient for the intended use and no degradation of display occurs when adding objects or documents to an opened session
- The voice commands can be used in operating room as long as the ambient noise does not exceed 60dB
- The performance of the Microsoft® HoloLens 2 display used with Cysart® 4H is adequate and has been demonstrated by verifying: luminance, distortion, contrast, and motion-to photon latency.

9. Clinical Data

Clinical testing was not required to demonstrate substantial equivalence.

10. Conclusion

Cysware® 4H and Cysart® 4H have the same intended use and the same technological characteristics that the predicate devices. It can be demonstrated that the devices are substantially equivalent to the predicate devices, and that these new devices don't raise additional questions regarding its safety and effectiveness as compared to the predicate devices.

The indications for use, features, and technological characteristics of the Cysware® 4H and Cysart® 4H are identical to the predicate devices. The overall indications for use, features, and technological characteristics data lead to the conclusion that Cysware® 4H and Cysart® 4H are substantially equivalent to legally marketed predicate devices.