Coreline Soft Co., Ltd.
% Hyeyi Park
Deputy General Manager/ Strategic Business Dept.
4, 5F (Yeonnam-dong), 49, World Cup buk-ro 6-gil, Mapo-gu
Seoul, 03991
KOREA

December 20, 2019

Re: K192040
Trade/Device Name: AVIEW Modeler
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 25, 2019
Received: November 26, 2019

Dear Hyeyi Park:

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)*
K192040

Device Name
AVIEW Modeler

Indications for Use *(Describe)*
The AVIEW Modeler is intended for use as an image review and segmentation system that operates on DICOM imaging information obtained from a medical scanner. It is also used as a pre-operative software for surgical planning.
3D printed models generated from the output file are for visualization and educational purposes only and not for diagnostic use.

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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K192040

510(k) Summary

1 SUBMITTER

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Contact Person: Hyeyi. Park
Date Prepared: July 30.2019

2 DEVICE

Name of Device: AVIEW Modeler
Common or Usual Name: AVIEW Modeler
Classification Name: System, image processing, radiological (21CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

3 PREDICATE DEVICE

D2P by 3D Systems, Inc. (K161841)
This predicate has not been subject to a design-related recall

4 REFERENCE DEVICE

Mimics inPrint by Materialise N.V. (K173619)
AVIEW by Coreline Soft Co., Ltd. (K171199)
This reference device has not been subject to a design-related recall

5 DEVICE DESCRIPTION

The AVIEW Modeler is a software product which can be installed on a separate PC, it displays patient medical images on the screen by acquiring it from image Acquisition Device. The image on the screen can be checked edited, saved and received.

- Various displaying functions
  - Thickness MPR., oblique MPR, shaded volume rendering and shaded surface rendering.
  - Hybrid rendering of simultaneous volume-rendering and surface-rendering.
- Provides easy to-use manual and semi-automatic segmentation methods
  - Brush, paint-bucket, sculpting, thresholding and region growing.
  - Magic cut (based on Randomwalk algorithm)

- Morphological and Boolean operations for mask generation.
- Mesh generation and manipulation algorithms.
  - Mesh smoothing, cutting, fixing and Boolean operations.
- Exports 3d-printable models in open formats, such as STL.
- DICOM 3.0 compliant (C-STORE, C-FIND)

6 INDICATIONS FOR USE

The AVIEW Modeler is intended for use as an image review and segmentation system that operates on DICOM imaging information obtained from a medical scanner. It is also used as a pre-operative software for surgical planning.
3D printed models generated from the output file are for visualization and educational purposes only and not for diagnostic use.

7 COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCIE

AVIEW Modeler has the same intended use and principle of operation, and also has similar features to the predicate devices, D2P(K161841)
There might be slight differences in features and menu, but these differences between the predicate device and the proposed device are not so significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that the proposed device is substantially equivalent to the predicate devices.

Characteristic	**Subject Device**	**Primary Predicate Device**	**Reference Device**	**Reference Device**
Device Name	**AVIEW Modeler**	**D2P**	**Mimics inPrint**	**AVIEW**
Classification Name	System, image Processing Radiological	System, image Processing Radiological	System, image Processing Radiological	System, image Processing Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ	LLZ	LLZ
Review Panel	Radiology	Radiology	Radiology	Radiology
510k Number	-	K161841	K173619	K171199
Indications for use	The AVIEW Modeler is intended for use as a software interface and image segmentation system that send DICOM imaging information through output file on a medical scanner. 3D model and 3D printed models generated by our software can also	The D2P Software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file it is also intended as pre-operative software for	Mimics inPrint is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file it is also used as pre-operative software for treatment	AVIEW provides CT values for pulmonary tissue from CT thoracic datasets. This software can be used to support the physician quantitatively in the diagnosis. Follow-up evaluation and documentation of CT lung tissue images by

	be used for a surgical plan and simulation use.	surgical planning. 3D printed models generated from the output file are meant for visual, non-diagnostic use.	planning for this purpose, the Mimics output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods.	providing image segmentation of sub-structures in the left and right lung (e.g., the five lobes and airway), volumetric and structural analysis, density evaluations and reporting tools. AVIEW is also used to store, transfer, inquire and display CT data sets. AVIEW is not meant for primary image Interpretation in mammography.
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network	IBM-compatible PC or PC network
User Interface	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard	Monitor, Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from card readers, or imported from a radiographic imaging device
32bit/64bit	64bit	64bit	32t/4bit	64bit
Image format	DICOM	DICOM	DICOM	DICOM
Image viewing	Axial, sagittal, and coronal image, oblique slice, 3D	Axial, sagittal and coronal images, oblique slice, 3D	Axial, sagittal and coronal images, oblique slice, 3D	Axial, sagittal and coronal images, oblique slice, cube view, 3D
Image manipulation	Panning, rotating, zooming, windowing, Coloring, Oblique, Note (text overlay), Coloring (volume of interest overlay)	Panning, rotating, zooming, windowing, region of interest overlay (ROI)	Panning, rotating, zooming, windowing, region of interest overlay (ROI)	Panning, rotating, zooming, windowing, inverting, Coloring, Oblique, Note (text overlay), Coloring (volume of interest overlay)
General Description	The AVIEW Modeler is a software product which can be installed on a separate PC, it displays patient medical images on the screen by acquiring it from Image Acquisition Device. The image on the screen can be checked edited, saved and	The D2P software is a stand-alone modular software package that allows easy to use and quick digital 3D model preparation for printing or use by third party applications. The software is aimed at usage by medical staff, technicians,	Materialise's Interactive Medical image Control System (mimics) is a software tool for visualizing and segmenting medical images (such as CT and MRI) and rendering 3D objects. Mimics inPrint may be used as a medical	The AVIEW is a software product which can be installed on a PC. It shows images taken with the interface from various storage devices using DICOM 3.0 which is the digital image and communication standard in medicine. It also offers functions

	received.	nurses, researchers or lab technicians that wish to create patient specific digital anatomical models for variety of uses such as training, education, and pre-operative surgical planning. The patient specific digital anatomical models may be further used as an input to a 3D printer to create physical models for visual, non-diagnostic use. This modular package includes, but is not limited to the following functions: ● DICOM viewer and analysis ● Automated segmentation ● Editing and pre-printing ● Seamless integration with 3D Systems printers ● Seamless integration with 3D Systems software packages	device. Within the limits of the described below intended use statement. Mimics may be used to load and process stack of 2D images from numerous formats including DICOM 3.0 format, BMP, TIFF, JPG and raw images. Once images are processed, they can be used	such as reading. Manipulation, analyzing, post-processing, saving and sending images by using the software tools.
DICOM	This receives DICOM data from CT or MRI by DICOM communication Conducts DICOM data communication with PACS. It also imports DICOM file directly, saves by using export function.	Retrieve image data over the network via DICOM	Retrieve image data over the network via DICOM	This receives DICOM data from CT or MRI by DICOM communication Conducts DICOM data communication with PACS. It also imports DICOM file directly, saves by using export function.
3D Modeling Functions	Providing ray sum image, axial, sagittal, coronal, and oblique planes.	Providing axial, sagittal, coronal, and oblique planes	Providing axial, sagittal, coronal,	Providing ray sum image, axial, sagittal, coronal, and oblique planes
	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction	Rotating to Anterior, Posterior, Left, Right, Head, and Foot direction
	Providing VR	Providing VR	Providing VR	Providing VR

	(Volume render), MIP (Maximum Intensity Projection), MinIP (Minimum Intensity Projection) image	(Volume render)	(Volume render)	(Volume render), MIP (Maximum Intensity Projection), MinIP (Minimum Intensity Projection) image
	Changing the color and transparency of the VR image by adjusting the OTF (Opacity Transfer Function) and saving as a preset to easily apply in the VR setting.	Changing the color and transparency of the VR image by adjusting the OTF (Opacity Transfer Function) and saving as a preset to easily apply in the VR setting.	-	Changing the color and transparency of the VR image by adjusting the OTF (Opacity Transfer Function) and saving as a preset to easily apply in the VR setting.
	Providing options of ambient, diffuse, specular, gradient, shininess, lighting and transient quality in the Camera setting	-	-	Providing options of ambient, diffuse, specular, gradient, shininess, lighting and transient quality in the Camera setting
	Saving the segmented region from the whole volume and converting to the surface model	Saving the segmented region from the whole volume and converting to the surface model	Saving the segmented region from the whole volume and converting to the surface model	-
	Saving the surface model in STL format	Saving the surface model in STL format	Saving the surface model in STL format	-
	The decimation and smoothing options can be applied when saving in STL format	The fixed decimation and smoothing options can be applied when saving in STL format	The decimation and smoothing options can be applied when saving in STL format	-
	Providing a model fixing function that can detect and correct errors on the surface model.	-	Model fixing of Surface model	-
	Boolean operation (Union, Subtract, Intersect) and segmentation function between models.	-	Boolean operation (Union, Subtract, Intersect)	-
	Creating Box, Sphere, Pipe, or Cone shape surface model	Creating Pipe shape surface model	Creating Box, Sphere, Pipe, or Cone shape surface model	-
	AVIEW Modeler provide segmentation function in the CT image. Key Features; Threshold, Region Grow, 3D Pick, ROI,	The D2P provide segmentation function in the CT image. Key Features; Threshold, Brush, (3D) Pick	The Mimics inPrint provide segmentation function in the CT image. Key Features; Threshold, Brush, Lasso, 3D	-

	Draw, Erase, Selective Brush, (3D) Sculpt & Paint, (2D,3D) Pick, Fill hole, Magic cut(semi-auto)		interpolates, split(semi-auto), Combine, Unite, Intersect, Subtract	

8 PERFORMANCE DATA

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

- Unit test
  Conducting Unit Test using Google C++ Unit Test Framework on major software components identified by software development team. List of Unit Test includes Functional test condition for software component unit, Performance test condition, and part of algorithm analysis for image processing algorithm.

- System test
  In accordance with the document 'integration Test Cases' discussed in advanced by software development team and test team, test is conducted by installing software to hardware with recommended system specification. Despite Test case recognized in advance was not in existence. New software error discovered by 'Exploratory Test' conducted by test team will be registered and managed as new test case after discussion between development team and test team.
  Discovered software error will be classified into 3 categories as severity and managed.
  - ✓ Major defects, which are impacting the product's intended use and no workaround is available.
  - ✓ Moderate defects, which are typically related to user-interface or general quality of product, while workaround is available.
  - ✓ Minor defects, which aren't impacting the product's intended use. Not significant.

  Success standard of System Test is not finding 'Major', 'Moderate' defect.

- Performance test
  In order to check whether the non-functional requirement indicated in section 'Performance and Non-Functional Requirements is satisfied, operate a test according to the performance evaluation standard and method that has been determined with prior consultation between software development team and testing team

- Compatibility test
  All 3D printer software's should validate imported STL file before 3D printing. STL data which is created by AVIEW Modeler imported into Stratasys printing Software, Object Studio to validate the STL before 3d-printing with Objet260 Connex3. (data compatibility between two software's)

9 CONCLUSIONS

The new device and predicate device are substantially equivalent in the areas of technical characteristics, general functions, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the AVIEW Modeler described in this submission is substantially equivalent to the predicate device