November 8, 2017

EndoVantage, LLC
% H. Semih Oktay, Ph.D.
Regulatory Consultant
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1783 Forest Drive, Suite 254
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Re: K171534
Trade/Device Name: SurgicalPreview
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: PZO
Dated: October 6, 2017
Received: October 10, 2017

Dear Dr. Oktay:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K171534

Device Name
EndoVantage SurgicalPreview

Indications for Use *(Describe)*
SurgicalPreview enables visualization and measurement of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. SurgicalPreview also allows for the ability to computationally model the placement and deployment of neurointerventional devices.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of CT scan images for 2D review and 3D reconstruction
- Measurement and annotation tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

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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510(k) SUMMARY K171534

Submitter: EndoVantage, LLC
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Contact Person: Robert S. Green
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Summary Date: October 6, 2017

Device Trade Name: SurgicalPreview™

Device Common Name: Radiological Image Processing Software

Device Classification Name: Software for visualization of vascular anatomy and intravascular devices

Regulatory Description: Picture Archiving and Communication System

Regulation Number: 21 CFR 892.2050

Product Code: PZO

Regulatory Classification: Class II

Predicate Device: EndoSize (K160376)

Device Description

SurgicalPreview™ is a stand-alone software application that runs on any standard Windows or Mac OSX based computer. It enables physicians to upload patient CT scan studies from various data sources, view them, and process the images. SurgicalPreview™ provides a clinical decision support system during the preoperative planning of endovascular surgery.

SurgicalPreview™ enables visualization and measurement of different vascular structures such as vessels, aneurysms, and other anomalies. SurgicalPreview™ also allows for the ability to computationally model the placement and deployment of neurointerventional devices. SurgicalPreview™ can reconstruct 2D scan slices into 3D models of the patient, and can display supporting DICOM CT scan data. It works with DICOM CT scan images and can access multiple DICOM data files.

The device does not contact the patient, nor does it control any life sustaining devices. Information provided by the software is not intended in any way to eliminate, replace or

substitute for, in whole or in part, the healthcare provider's judgement and analysis of the patient's condition.

Indications for Use
SurgicalPreview™ enables visualization and measurement of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. SurgicalPreview™ also allows for the ability to computationally model the placement and deployment of neurointerventional devices.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of CT scan images for 2D review and 3D reconstruction
- Measurement and annotation tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgement and analysis of the patient's condition.

Technological Characteristics
SurgicalPreview™ is a software-only device that runs on a standard computer that meets the minimum requirements. SurgicalPreview™ is not intended for use on mobile devices.

SurgicalPreview™ can use local DICOM files. The device does not contact the patient, nor does it control any life sustaining devices. Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgement and analysis of the patient's condition.

Performance Data
The subject device is designed in conformance with:

- ACR/NEMA Digital Imaging Communications in Medicine (DICOM) Version 3.1
- ISO 14971:2007 – Medical Devices – Application of Risk Management to Medical Devices
- IEC 62304:2006 – Medical Device Software – Software Life-Cycle Processes

All specifications of the SurgicalPreview™ software are validated by a bench test before release. Bench testing includes:

- Tests of importation of DICOM images
- Patient manager tests
- Tests of image display and processing
- Functioning tests for visualization of anatomic reconstruction
- Functioning tests for computational modeling of Codman Enterprise Vascular Reconstruction Device and Pipeline Embolization Device

- Measurement tests
- Reports creation and visualization tests

Predicate Device Comparison

The predicate device for the SurgicalPreview™ software is EndoSize (K160376). Both SurgicalPreview™ and its predicate device have similar intended use for preoperational planning of endovascular procedures using image data from a medical scanner. A summary comparison of technological characteristics is provided in Table 1.

Table 1 - SurgicalPreview™ and Predicate Comparative Analysis

Characteristic	SurgicalPreview™	Predicate: EndoSize
510(k) Number	K171534	K160376
Indications for Use	SurgicalPreview™ enables visualization and measurement of vessels for preoperational planning and sizing for neurovascular interventions and surgery. SurgicalPreview™ also allows for the ability to computationally model the placement and deployment of neurointerventional devices.	EndoSize enables visualization and measurement of structures of the heart and vessels for preoperational planning and sizing for cardiovascular interventions and surgery, and for postoperative evaluation
Interface to Image Sources	DICOM image data	Same
Import of Patient Data	Manual through keyboard/mouse, automatic import with image file, study creation list	Same
List Image Functionality	Deleting, anonymizing, search	Same
Image Processing	Segmentation by EndoVantage operator with end-user clinician review and comment	By clinician
3D Assessment	Linear (length and diameter) measurements, volume measurements	Same
Image and 3D Display	Orthogonal, color volume rendering, 2D slice review, active presets, 3D view of assemblies of devices	Same
DICOM Support	Compatible with all scanner vendor DICOM datasets, storage SCP, import DICOM files, DICOM compliance for CT and enhanced CT, import from DICOMDIR, storage SCU, query/retrieve SCU	Same
Computer OS Compatibility	MS Windows and Mac OS	Same
Data Interchange / Transfer Method	Secure Internet File Server	Personal computer
Output File Format	Web browser via WebGL	Personal computer

Characteristic	SurgicalPreview™	Predicate: EndoSize
Preoperational Planning	Yes	Same
Patient Contact	No	Same
Human Intervention for Interpretation of Images	Yes	Same

Substantial Equivalence Conclusion

Based on the information provided in this 510(k) submission, SurgicalPreview™ has the same intended use as the predicate device. SurgicalPreview™ underwent bench testing to simulate clinical use. The performance data and software verification and validation results demonstrated that the differences in technological characteristics between SurgicalPreview™ and the predicate device do not raise different questions of safety and effectiveness and that SurgicalPreview™ should perform as intended in the specified use conditions. EndoVantage concludes that SurgicalPreview™ is substantially equivalent to the predicate device identified in this submission.