DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 28, 2017

OSKO, Inc.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K163048
Trade/Device Name: Smart Stitching Software
System, Image Processing, Radiological
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 25, 2017
Received: July 26, 2017

Dear Mr. Kim:

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,

Michael D. O'Hara 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.

510(k) Number *(if known)*

K163048

Device Name
Smart Stitching Software
System, Image Processing, Radiological

Indications for Use *(Describe)*

Smart Stitching software is indicated for use to allow post-capture positioning and joining of individual images to produce an additional composite image for two dimensional image review.

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

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: June 22, 2017

I. SUBMITTER

Submitter's Name	OSKO, Inc.
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II. DEVICE

Trade/proprietary Name	Smart Stitching software
Common or Usual Name	System, Image Processing, Radiological
Regulation Name	Picture archiving and communications system
Regulation Number	21 CFR 892.2050 (Product Code:LLZ)
Regulatory Class	Class II

III. PREDICATE DEVICE

Primary Manufacturer	Cedara Software Corporation
Device Name	Cedara I-Soft View
510(k) Number	K022881
Regulation Name	Picture archiving and communications system
Regulation Number	21 CFR 892.2050 (Product Code:LLZ)
Regulatory Class	Class II

IV. REFERENCE DEVICE

Primary Manufacturer	Carestream Health Inc
Device Name	DR Long Length Imaging Software
510(k) Number	K130567
Regulation Name	Solid Stat X-ray Imager
Regulation Number	21 CFR 892.1650 (Product Code:MQB)
Regulatory Class	Class II

V. DEVICE DESCRIPTION

Smart Stitching provides a function to read multiple medical images at one time by stitching them to one image based on overlapping areas. It supports DICOM 3.0 which is standard of medical image format as well as Tiff and Raw images. It provides additional functions such as image retrieval, storage, and transmission. Smart Stitching is designed to facilitate diagnosis by easily stitching multiple medical images, up to 5 images, from multiple captures to one image.

Smart Stitching software does not serve as acquisition software nor has control function for acquisition setting.

VI. INDICATIONS FOR USE:

Smart Stitching software is indicated for use to allow post-capture positioning and joining of individual images to produce an additional composite image for two dimensional image review.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Feature	New Device Smart Stitching K163048	Reference Device DR Long Length Imaging Software K130567	Predicate Device Ceara I-SoftView K022881
Manufacturer	OSKO, Inc.	Carestream Health Inc.	Cedara Software
Intended Use	Smart Stitching software is indicated for use to allow post-capture positioning and joining of individual images to produce an additional composite image for two dimensional image review.	The software intended use is to allow post-capture positioning and joining of individual images to produce an additional composite image. The software is sold only for use on Carestream Health System solutions and is available as an integrated feature within the DirectView software	"Two and three dimensional image review, manipulation, analysis and therapy planning capabilities that support image management display needs in the medical environment from multiple locations within and outside the hospital" "Productivity-Enhancing Second Console Workstations - Workstations designed to perform automated, routine tasks such as image review, printing and archiving as well as post processing capabilities that enable special services for referring physicians." "Diagnostic Review Workstations - Workstations designed to assist radiologists and surgeons in conducting primary diagnostic review and planning through flexible and interactive manipulation of multi-modality softcopy images. This includes the use of prosthetic template overlays" "Physician's Review Workstations - Workstations designed to give easy and economic access to multi-modality softcopy images in multiple locations within

			and outside the hospital. (e.g. teleconferencing, teleradiology etc.)"
How to store patient data an diagnostic documents	Be comprised of a central database to store patient data and diagnostic documents	Be comprised of a central database to store patient data and diagnostic documents	Be comprised of a central database to store patient data and diagnostic documents
Type of image format	Tiff, Raw, and DICOM file	DICOM file	DICOM file
Ability to provide the management, storage and processing and display of patient, diagnostic image data	Provide the management, storage and processing and display of patient, diagnostic image data	Provide the management, storage and processing and display of patient, diagnostic image data	Provide the management, storage and processing and display of patient, diagnostic image data
Function to enhance image brightness, contrast and sharpness	Provide functions to enhance image, zoom in/out, brightness, contrast and sharpness	Provide functions to enhance image brightness, contrast and sharpness	Provide functions to enhance image brightness, contrast and sharpness
Function to search to retrieve medical records lined to a specific patient	a search function to retrieve medical records linked to a specific patient	a search function to retrieve medical records linked to a specific patient	a search function to retrieve medical records linked to a specific patient
Function to export and import data	Include a function to export and import data	Include a function to export and import data	Include a function to export and import data

Function to print out the stored data	Can produce printouts of the stored data	Can produce printouts of the stored data	Can produce printouts of the stored data
Function to connect to LAN and have DICOM interface	Can connect to LAN and have DICOM interface (by default or as a separate option)	Can connect to LAN and have DICOM interface (by default or as a separate option)	Can connect to LAN and have DICOM interface (by default or as a separate option)

VIII. COMPARISON DISCUSSION

The indications for use statement for the subject device is similar to indications for use of the predicate device based on the description and the proposed labeling contained in this submission. Both the subject and the predicate software aligns captured images to stitch and generate a long-length composite image, while fine adjustments can be made using the manual stitch editor. The differences in the indications for use for the subject and predicate device, such as the image file type, do not affect the intended diagnostic use of the software. Smart Stitching software has the same technological characteristics as the reference device and the predicate device,"DR Long Length Imaging Stitching" and Cedara I-Softview "Accustitch" respectively. These devices allow a composite image to be formed from multiple general radiography images acquired separately. The new software device raises no new issues of safety or effectiveness.
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No clinical testing is performed.

The complete system configuration has been assessed and tested by the manufacturer and passed all in house testing criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by Smart Stitching Software. Each operational mode and the imaging stitching process are documented in the software validation report.

The auto stitching function and SW compatibility test have been conducted and the result demonstrated that the software functions as intended. In addition, the software validation testing ,from TS-0001 through TS-0017, verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Safety and Performance Data:

- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007

- NEMAPS 3.1-3.20 – Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)

IX. CONCLUSIONS

Based on the information above, it is the sponsor's opinion that Smart Stitching software is substantially equivalent to the predicate software in design and performance.
The differences between Smart Stitching software and its predicate do not raise different questions of safety and effectiveness.