Kinepict Health, Ltd.
℅ Ms. Lilla Strobel
Quality and Regulatory Manager
Kelta k z
Budakeszi, H-2092
HUNGARY

March 5, 2020

Re: K190993
Trade/Device Name: Kinepict Medical Imaging Tool version v2.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 29, 2020
Received: January 29, 2020

Dear Ms. Strobel:

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)*
K190993

Device Name
Kinepict Medical Imaging Tool version v2.2

Indications for Use *(Describe)*
Kinepict Medical Imaging Tool version v2.2 is intended to be used to visualize blood vessel structures by detecting the movement of the contrast medium bolus in standard-of-care angiography examination. This software is intended to be used in addition to, or as replacement for current DSA imaging.

Kinepict Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, Kinepict Software can be deployed on systems of several angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

Kinepict Software can also be combined with fluoroscopy systems or Radiographic systems.

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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6. 510(k) Summary

510(K) Summary: Kinepict Health Imaging Tool

Company: Kinepict Health Ltd
2092 Kelta köz 5.
Budakeszi, Hungary

Date Prepared:

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information:

Importer/Distribution

Kinepict Health Ltd
2092 Kelta köz 5.
Budakeszi, Hungary

Manufacturing Site:

Kinepict Health Ltd
1025 Budapest Júlia utca 11
Budapest, Hungary

Contact Person

Ms. Lilla Strobel
Quality Assurance Manager
Kinepict Health Ltd Hungary
1025 Budapest Júlia utca 11
Budapest, Hungary
Phone: +36317852260
Email: lilla.strobel@kinepict.com

Device Name and Classification:

Trade Name: *Kinepict Medical Imaging Tool* version v2.2

Classification Name: Picture Archiving and Communications system

Classification Panel: Radiology

Classification Regulation: 21 CFR §892. 2050

Device Class: Class II

Product Code: LLZ

Legally Marketed Predicate Device

Trade Name: Syngo Application Software VD11

510(k) Clearance K153346

Clearance Date February 24, 2015

Classification Name: Picture Archiving and Communications System

Classification Panel: Radiology

CFR Section: 21 CFR §892. 2050

Device Class: Class II

Product Code: LLZ

Recall Information: This predicate device has not been the subject of any design related recalls.

a. Device Description:

The *Kinepict Medical Imaging Tool* is medical diagnostic software for real-time viewing, diagnostic review, post-processing, image manipulation, optimization, communication, reporting and storage of medical images and data on exchange media. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. It can be deployed with Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346) or Windows based software options, which are intended to assist the physician in evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Kinepict Medical Imaging Tool is designed to work with digital radiographic, fluoroscopic, interventional and angiographic systems. The software platform with common software architecture, *platform*

Kinepict Health Ltd Hungary. hereby submits this Traditional 510(k) to request clearance for the Subject Device (*Kinepict Medical Imaging Tool*).

b. Intended use

Kinepict Medical Imaging Tool version v2.2 is intended to be used to visualize blood vessel structures by detecting the movement of the contrast medium bolus in standard-of-care angiography examination. This software is intended to be used in addition to, or as replacement for current DSA imaging.

Kinepict Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data. Furthermore, Kinepict Software can be deployed on systems of several angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

Kinepict Software can also be combined with fluoroscopy systems or Radiographic systems.

c. Substantial Equivalence

The Kinepict software has the same intended use as the Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346)workstation software. Between the two software is one important difference that Kinepict sotfware image proccessing algorythm optimised to calculate the Kinetic images, and Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346) optimised to DSA images. Between the postprocessing functions: contrast and brightness settings, choosing mask image, pixel shift applications and anonimising

options has been proven to similar in two software. Image storing and image sending functions are used the same DICOM technic and ports as Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346).

These differences do not have an effect on safety and efficiency compared with the predicate software. In summary, the Kinepict software does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

In conclusion, the Kinepict is substantially equivalent to Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346).

d. Performance Data

a. Clinical data

The statistical description of the visual comparison of the image pairs was divided into two parts. First agreement of the clinicians (inter-rater reliability) was determined using percentages of agreement and Fleiss' kappa calculations (kappa and p values). Thereafter the proportion of answers (which image is better in the given comparison) with 95% confidence interval was determined. Calculations were made by Stata 15.0 statistical data analysis software (StataCorp, Texas, USA).

Clinical Study

The performance of the Kinepict Medical Imaging Tool and the Digital Variance Angiography (DVA) technology was tested in two prospective observational clinical studies on patients with Peripheral Artery Disease (PAD, Fontaine IIa-IV) involving 42, using iodinated contrast media (ICM).

Comparison of the performance of DSA and DVA in lower limb X-ray angiography using ICM

The clinical study was a monocentric prospective, non-randomized, single-arm study of 42 patients with symptomatic PAD. Enrolled 42 participants undergoing lower-limb x-ray angiography between February and June 2017 (mean age, 68.7 years; age range, 49–89 years; 32 men [mean age, 67.1 years; age range, 49–89 years] and 10 women [mean age, 75 years; age range, 57–85 years The patients received the

standard clinical care before, during and after the angiographic procedures, the institutional protocols were not modified in any aspect. The DVA images were generated retrospectively from the raw data obtained from a Siemens Artis Zee with Pure angiography system at the Heart and Vascular Center, Budapest, Hungary (HVC). The DSA images were generated by the Siemens Syngo workstation (XWP VD11B Service Pack 2), the DVA images were generated by the KMIT software.
Primary effectiveness endpoints and results:
The signal-to-noise ratio (SNR) and the visual quality of DVA and DSA images were evaluated. SNR comparison. A total of 1902 regions of interest were carefully selected in 110 image pairs to calculate and compare the SNRs. The overall median SNR of DVA images was 2.3-fold higher than that of DSA images. Visual evaluation. The quality of 238 pairs of DSA and DVA images was compared by 6 clinical experts (vascular surgeons and interventional radiologists with a clinical experience of at least 8 years) in a blinded, randomized manner. Raters judged the DVA images better in 69 % of all comparisons. The interrater agreement was 81% and Fleiss κ was 0.17 ($P < .001$). For further details see our publication (Gyano et al, 2019, Radiology, 290:146-253).

Summary and Conclusions

Our clinical studies provided evidence that the DVA images generated by the KMIT software have higher SNR and better image quality than the DSA images generated by the Syngo workstation, thus the effectiveness profile of KMIT is at least as good as that of the predicate device. As an additional tool, it does not raise any additional risk comparing to the predicate device.

The most important datasets confirming our claims are:

- Kinetic images provided 3.3 times (median) and 2.3 times (median) better Signal to Noise Ratio(SNR) than raw and post-processed DSA images, respectively.
- Six specialists compared 238 pairs of kinetic and DSA images, and the LA (level of agreement) was > 73% ($p > 0.0001$) that kinetic imaging provided higher quality

images than DSA obtained from Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346).

b. Non-Clinical Data

The purpose of the test was to compare the signal-to-noise ratio (SNR) of digital variance angiograms (DVA) and digital subtraction angiograms (DSA). All DVA images were created using Kinepict Medical Imaging Tool v2.2.0.47 All DSA images were created using Siemens syngo VD11. The same set of X-ray angiographic (XA) series were used to create DVA and DSA images. There are 4 main steps of the test.

Step 1.: Data used: XA series acquired as part of the clinical study: 2830/2017

Results: 45 anonymized XA series from multiple patients along with corresponding DSA images were successfully selected adhering to the selection criteria.

Step 2.: Data used: 45 XA series selected in Step 1.

Results: All DVA images were successfully created using Kinepict Medical Imaging Tool v2.2.0.476. The images were successfully stored as DICOM files.

Step 3.: Data used: 45 DSA images selected in Step 1 and 45 DVA images created in Step 2 with 45 previously created corresponding ROI sets loaded from the clinical study dataset.

Results: ROI sets were successfully applied to DVA and DSA images. ROI's showed no misplacement, confirming that the vascular anatomy visible on DVA and DSA images do not differ. Result tables were successfully generated using the ImageJ script. The tables were arranged and the SNR values and ratios were successfully calculated.

Step 4.: Data used: 45 DSA images selected in Step 1 and 45 DVA images created in Step 2 with 45 previously created corresponding ROI sets loaded from the clinical study.

Conclusion

The non clinical test concluded that DVA images created using Kinepict Medical Imaging Tool v2.2.0.476 provides better signal to noise ratio than DSA images created using Syngo Application Software VD11 (Siemens Medical Solutions USA Inc. under K153346). Therefore the substantial equivalence is proven.