September 10, 2021

Kinepict Health Ltd
℅ Lilla Strobel
Quality and Regulatory Manager
Kelta köz 5
Budakeszi 2092
HUNGARY

Re: K202056
    Trade/Device Name: Kinepict Medical Imaging Tool 4.0
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Medical Image Management and Processing System
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: August 9, 2021
    Received: August 9, 2021

Dear Lilla 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

Indications for Use

510(k) Number *(if known)*
K202056

Device Name
Kinepict Medical Imaging Tool 4.0

Indications for Use *(Describe)*

Kinepict Medical Imaging Tool version 4.0 (KMIT v4.0) is intended to be used to visualize blood vessel structures by detecting the movement of the contrast bolus during angiography examination and to give the medical experts the option to reduce x-ray dose. The effectively achievable radiation reduction depends on the characteristics of the different cath labs (angiography unit, acquisition protocol, anatomical region) and requires the optimization of locally appled acquisition protocols. The software is intended to be used in addition to, or as a replacement for current DSA imaging. KMIT v4.0 can be deployed on independent workstation hardware for stand-alone diagnostic assessment, post-processing, reporting. It can be configured within a network to send and receive DICOM data. Furthermore, KMIT v4.0 can be deployed on several kinds of angiography systems. It provides solutions in the operating room for image-guided surgery, and image-guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. KMIT v4.0 can be also combined with fluoroscopic 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.

1. 510(k) Summary

K202056

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

1026 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

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Device Name and Classification:

Trade Name: *Kinepict Medical Imaging Tool*

Classification Name:	Medical image management and processing system.
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	LLZ

Legally Marketed Predicate Device

Trade Name:	Kinepict Medical Imaging Tool 2.2
510(k) Clearance	K190993
Clearance Date	March 5, 2020
Classification Name:	Medical image management and processing 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* version 4.0 (KMIT v4.0) is medical diagnostic software for real-time viewing, diagnostic review, post-processing, 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, and image-guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. KMIT v4.0 can be deployed on independent workstation hardware for stand-alone diagnostic assessment, post-processing, reporting, which are intended to assist the physician in the evaluation of digital radiographic examinations, including diagnosis and/or treatment planning. *KMIT v4.0* is designed to work with digital radiographic, fluoroscopic, interventional, and angiographic systems. The algorithm behind the Digital Variance Angiography (DVA) image calculation is the same in KMIT v2.2 (Kinepict Health Ltd. under

K190993) and v4.0 (see Device Description / Calculation of DVA section). The post-processing functions like contrast and brightness settings, choosing mask image, pixel shift applications, and anonymizing options are the same in the two software. Image storing and image sending functions are using the same DICOM technic and ports as Kinepict Medical Imaging Tool v2.2. In v4.0 automatic upload to PACS and automatic opening of screen size view is implemented. These differences do not have any effect on safety and efficiency. In summary, the KMIT v4.0 software does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

b. Intended use

Kinepict Medical Imaging Tool version 4.0 (KMIT v4.0) is intended to be used to visualize blood vessel structures by detecting the movement of the contrast bolus during angiography examination and to give the medical experts the option to reduce x-ray dose. The effectively achievable radiation reduction depends on the characteristics of the different cath labs (angiography unit, acquisition protocol, anatomical region) and requires the optimization of locally appled acquisition protocols. The software is intended to be used in addition to, or as a replacement for current DSA imaging. KMIT v4.0 can be deployed on independent workstation hardware for stand-alone diagnostic assessment, post-processing, reporting. It can be configured within a network to send and receive DICOM data. Furthermore, KMIT v4.0 can be deployed on several kinds of angiography systems. It provides solutions in the operating room for image-guided surgery, and image-guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. KMIT v4.0 can be also combined with fluoroscopic or radiographic systems.

c. Substantial Equivalence

The Kinepict software has the same intended use as the Kinepict Medical Imaging Tool v2.2 (Kinepict Health Ltd. under K190993) software, but the performance with lower x-ray dose is clinically proven. Between the postprocessing functions: contrast and brightness settings, choosing mask image, pixel shift applications and anonimising options are the same in two

software. Image storing and image sending functions are used the same DICOM technic and ports as Kinepict Medical Imaging Tool v2.2 (Kinepict Health Ltd. under K190993).

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 Kinepict Medical Imaging Tool v2.2 (Kinepict Health Ltd. under K190993).

d. Performance Data

a. Clinical data

Digital Variance Angiography allows reduction of radiation exposure in X-ray angiography

The dose management capability of the Kinepict Medical Imaging Tool and the Digital Variance Angiography (DVA) technology was tested in a prospective interventional clinical study on Peripheral Artery Disease (PAD) patients. The aim was to investigate whether the previously observed quality reserve of DVA can be used for the reduction of DSA-related radiation exposure during lower X-ray angiography using ICM.

Our prospective study enrolled 30 PAD patients (Fontaine IIb-IV, mean age 70 years, range 52-85 years; 10 females, mean age 73 years, range 55-85 years; and 20 males, mean age 69 years, range 52-85) undergoing diagnostic lower limb X-ray angiography between April and July 2019. In all enrolled patients, both normal and low-dose protocols were used for the acquisition of images in three anatomical regions (abdominal, femoral, crural). The contrast-to-noise ratio (CNR) of DSA and retrospectively generated DVA images were calculated, and the quality was evaluated by seven specialists using a 5-grade Likert scale. For investigating non-inferiority, the difference of low-dose DVA (ldDVA) and normal dose DSA (ndDSA) scores was analyzed by the one-sample Wilcoxon test. The diagnostic value of low-dose DVA images was compared to that of normal dose DSA images in a task-based survey, where six readers were asked to identify the different artery segments, and evaluate the degree of stenosis

on a 5-grade scale. The endpoints were the number of recognized arteries, the proportion of arteries suitable for diagnostic evaluation, and the sensitivity and specificity of low dose DVA images to obtain the same diagnostic category as the normal dose DSA images.

DVA produced consistently higher (two to threefold) CNR than DSA. The highest ratios (3.0-3.1) were observed in the crural region. In line with this, ldDVA received significantly higher visual evaluation scores in the crural region than ndDSA (difference 0.25±0.07, p=0.001). There was no significant difference in the femoral region (-0.08±0.06, p=0.435), but ndDSA received significantly higher score in the abdominal region (-0.26±0.12, p=0.036). However, after exclusion of patients with excessive intestinal gases (3/30, 10% of patients), the difference in the abdominal region decreased to (-0.10 ± 0.09, p=0.350) and was no longer significant. In the task-based diagnostic test there was no significant difference in the overall number of recognized arteries (ndDSA: 5.56 ± 0.01, ldDVA: 5.46 ± 0.01) and in the proportion of arteries suitable for diagnosis (ndDSA: 92.3 ± 0.1 %, ldDVA: 93.5 ± 0.1 %). ldDVA reproduced the ndDSA diagnostic categories with 0.84 sensitivity and 0.84 specificity. When the discordant decisions were supervised and the valid diagnostic category was determined by an expert, the accuracy of ndDSA and ldDVA was identical in the abdominal and femoral regions, but ldDVA had a highest accuracy in the crural region (91% vs 80%).

The described clinical investigation is a proof-of-concept study, which demonstrates that the previously verified quality reserve of DVA can be effectively converted into radiation dose reduction without compromising the image quality and diagnostic value of angiograms. The study was performed using a Siemens Artis Zee angiography system and Ultravist 370 iodinated contrast medium, and provided evidence for a substantial dose reduction during lower limb X-ray angiography. The effectively achievable radiation reduction depends on the characteristics of different cath labs (angiography unit, acquisition protocol, anatomical region) and requires the optimization of locally applied acquisition protocols. Nevertheless, this dose management capacity is based on the better image quality of DVA technology (a claim previously approved by FDA, see K190993), therefore a certain amount of radiation dose reduction will be achievable on other angiography systems as well.