Naviswiss AG
% Stefano Adami
Senior Consultant
confinis AG
Allee 1b
Sursee, 6210
SWITZERLAND

October 5, 2021

Re: K211429
Trade/Device Name: NAVIPLAN - CT Planning Software for Total Hip Replacement
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 26, 2021
Received: August 30, 2021

Dear Stefano Adami:

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)*
K211429

Device Name
NAVIPLAN - CT Planning Software for Total Hip Replacement

Indications for Use *(Describe)*
Naviplan is indicated for pre-operative planning for surgical procedures related to hip, such as artificial joint replacement (3D templating of implants)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K211429

5. 510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Applicant: Naviswiss AG

Submitter name: Jan Stifter

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Official Correspondent:

Contact person:	Stefano Adami
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Date prepared:	26 August 2021

Device Name: NAVIPLAN - CT Planning Software for Total Hip Replacement

Proprietary name:	NAVIPLAN - CT Planning Software for Total Hip Replacement
510(k) number:	To be assigned
Common name:	System, image processing, radiological
Classification name:	System, image processing, radiological
Product code:	LLZ

Predicate Device:

Substantial equivalence is claimed with the device, K1303022 “ZedView”, manufactured by Lexi Co., Ltd. on the basis of equivalent intended use / indications for use, technological characteristics, and principle of operation.

This predicate has not been subject to a design-related recall.

Device Description:

NAVIPLAN - CT Planning Software for Total Hip Replacement, or “Naviplan”, is a software which assists in the pre-operative planning of total hip replacement surgery based on three dimensional CT-images (computed tomography).

The Naviplan allows the user to process CT DICOM images which are automatically segmented. The user gets an automatic identification of anatomical landmarks as an output, which is normally used in hip surgery. The Naviplan automatically computes an initial planning (implant type and size selection as well as positioning) which can be inspected and edited by the user until the optimal configuration is established. The user can export

the plan as a pdf report and as a navigation archive to be used with the Naviswiss Hip Navigation System. The export steps are optional, whereas the report serves a documentation purpose.

Indications for Use:

Naviplan is indicated for pre-operative planning for surgical procedures related to hip, such as artificial joint replacement (3D templating of implants).

Comparison of Technological Characteristics:

Table 05-1 provides a comparison of the predominant technical characteristics of the subject device and the legally marketed predicate device. A more detailed comparison of the devices is presented in Section 12.

Description	Subject Device	Predicate Device
Device Name	Naviplan	ZedView (ZedHip)
510(k) Number	To be assigned	K133022
Manufacturer	Naviswiss AG	Lexi Co., Ltd.
Prescription device	Yes	Yes
Intended Use	Naviplan is intended to be used by a suitably licensed and qualified healthcare professional to access medical images with the intention of using such images, in conjunction with templates for prosthetic devices, for the purposes to assist qualified healthcare professional in choosing the nature and characteristics of the prosthetic device to be used when planning a potential surgical hip procedure. The software is basically intended to be standalone, however the planning data can be imported into the "Naviswiss System" (navigation system) for intra-operative use.	ZedView is intended to be used to assist qualified medical professionals to perform fast and effective pre-operative planning for various surgical procedures related to hip and knee by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers. ZedHip is the specific 3-Dimensional Pre-Op. Planning software for Total Hip Arthroplasty with CT images.
Indications for use	Naviplan is indicated for pre-operative planning for surgical procedures related to hip, such as artificial joint replacement (3D templating of implants).	Zed View is indicated for pre-operative planning for various surgical procedures related to hip and knee, such as artificial joint replacement (3D templating of implants) and osteotomy.
Principles of Operations	The user can manage a database of patients data and perform a pre-operative planning per patient. For each patient a hip DICOM series of a CT scan can be	The software primarily provides import and storage of CT images of various patients in DICOM or other formats which are automatically segmented by the software. ZedView

Description	Subject Device	Predicate Device
	loaded and automatically segmented. When the segmentation, which is done on the local computer, is completed, the user can edit the initialized case. While planning the user can try different configurations of implant types, sizes, positions, orientations and more. The planning view shows the user useful metrics such as resulting leg length, lateral offset, acetabular orientation, CCD-angle, femoral offset and femur antetorsion. The pre-operative planning can be exported in PDF format for printing or in the Naviswiss Hip Navigation System as a binary format for intra-operative use.	provides a means of 3D templating of implants and positioning of fixation devices by calculating surgical parameters in simulated environments and performing 3D measurements on each pre-operative patient data using 2D image viewing and manipulations, 3D visualizations and various MPR (Multi-Planar Reconstruction) functions. ZedHip is the software that supports pre-operative planning of hip arthroplasty from 2D digital X-ray images obtained with the EOS imaging and CT images.
Operating system	Windows or OS X	Windows
Availability of device	Can be configured to be launched from within a workstation environment or as a standalone PC application for planning orthopedic procedures.	Can be configured to be launched from within a workstation environment or as a standalone PC application for planning orthopedic procedures.
Source of images	Receive digital images from the computer or via USB stick	Receive digital images from various sources (including PACS system)
Processing of images	The software processes data in order to provide an overlap and dimensioning of digital representations of the prosthetic material	Scaling of image facility
Superimposing digital Prosthetic Templates	Allows the overlap of models and the intersection of the models	Permits overlay of templates
Interactive positioning of template	Yes	Yes
Interactive sizing of template	Yes	Yes
Permits template rotation	Yes	Yes
Provides templating support from prosthetic manufacturers.	Yes	Yes
Permits automatic scaling	Yes	Semi-automatic measurements
Pre-operative planning	Yes	Yes
Osteotomy module	No	Yes

Description	Subject Device	Predicate Device
Patient contact	None	None
Control of life sustaining devices	None	None
Human intervention for interpretation of images	Required	Required
Ability to add additional modules when available	Yes	Yes
Operating system	Windows or OS X	Windows

The technological principle for both the subject and predicate devices is to use DICOM image standards that are automatically segmented, and the software provides anatomical landmarks and an initial proposed planning that can be edited by the surgeon to find the best implant configuration and positioning. Both software can be configured to be launched from within a workstation environment or as a standalone PC application for planning orthopedic procedures related to the hip joint.

Both software can manage a database of patient's data and perform a pre-operative planning per patient based on DICOM series of a CT scan and allow different configurations of implant types, sizes, positions, orientations and more and show the user useful metrics such as resulting leg length, lateral offset, acetabular orientation, CCD-angle, femoral offset and femur antetorsion.

Naviplan has an additional feature that allows export of planning data to be used in the Naviswiss Hip Navigation system (K193034). This difference does not represent a substantial difference since it is just an export feature to allow visualization of the planned positioning of the orthopedic implant to the intraoperative navigation.

Summary of Testing:

The relevant requirements set forth in standards listed in Section 9 by the manufacturer are sufficient to assure a safe and effective functioning of the NAVIPLAN - CT Planning Software for Total Hip Replacement. The device has fulfilled the requirements detailed above. The results of the bench and performance testing are summarized in the verification and validation plan and report enclosed.

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This

software is considered as a “moderate” level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. Dedicated software verification testing has been conducted to compare manual segmentation and landmark positioning to the NAVIPLAN - CT Planning Software for Total Hip Replacement automated segmentation and planning.

Conclusion:

Based on equivalence of intended use / indications for use, technological characteristics and operational principle the applicant concludes, that substantial equivalence between the new and the predicate device has been demonstrated and that the new device, NAVIPLAN - CT Planning Software for Total Hip Replacement, is at least as safe and as effective as the legally marketed predicate device, Zedview (K133022).