June 10, 2020

Naviswiss AG
℅ Viky Verna
Co-Founder & VP (US Office)
confinis
15807 Glacier Ct
Potomac, Maryland 20878

Re: K193094
Trade/Device Name: Naviswiss Hip Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 5, 2020
Received: June 8, 2020

Dear Viky Verna:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
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)*
K193094

Device Name
Naviswiss Hip Navigation System

Indications for Use *(Describe)*
The Naviswiss Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes to aid in the positioning of orthopedic implant system components where a reference to a rigid anatomical structure can be identified. The system is only compatible with acetabular cup impactors that have a parallel and straight segment. The system aids the surgeon in performing intra-operative measurements including measurements of leg length, offset, and cup inclination/anteversion.

An example of a stereotaxic orthopedic surgical procedure includes Total Hip Arthroplasty: Lateral/Supine.

The equipment is intended for use by trained surgeons in operating theaters.

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.

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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:	Viky Verna, MS BME, MS Pharm, RAC
Phone:	786-525-9811
Email:	Viky.verna@confinis.com
Date prepared:	4 November 2019

Device Name: Naviswiss Hip Navigation System

Proprietary name:	Naviswiss Hip Navigation System
510(k) number:	To be assigned
Common name:	Orthopedic Stereotaxic Instrument
Classification name:	Orthopedic Stereotaxic Instrument
Product code:	OLO

Predicate Device:

Substantial Equivalence is claimed with the device, K162364 “intellijoint HIP Generation 2A System”, manufactured by Intellijoint Surgical Inc. on the basis of equivalent intended use / indications for use, technological characteristics and principle of operation.

Device Description:

The Naviswiss Hip Navigation System is an image-free surgical navigation system intended to assist the orthopedic surgeon during the implantation of an artificial joint (hip). The device consists of a handheld navigation device, used to register the patient’s anatomy into a software platform. Subsequently the navigation system helps the surgeon maneuver the surgical instruments with precision. Thus, the surgeon can position the implant in accordance to pre-operative planning.

The Naviswiss Hip Navigation System is comprised of two major sub-systems: the Naviswiss Hip (M42) and Naviswiss Platform (M59).

The Naviswiss Hip (M42) is composed of:

- NAVItags used for reference and registration
- Ancillary instruments
- Application Software

The Naviswiss Platform (M59) is composed of:

- Computer
- Camera
- Software

The M42 employs the base computing, power supply, and programing in the M59 Platform. The NAVItags allow the surgeon to determine anatomical landmarks or navigate an instrument.

The camera utilizes application and tracking software to guide the surgeon through a workflow process for the surgery. The camera is covered by a sterile, single use drape for use of the navigation device in a sterile environment.

Indications for Use:

The Naviswiss Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes to aid in the positioning of orthopedic implant system components where a reference to a rigid anatomical structure can be identified. The system is only compatible with acetabular cup impactors that have a parallel and straight segment. The system aids the surgeon in performing intra-operative measurements including measurements of leg length, offset, and cup inclination/anteversion.

An example of a stereotaxic orthopedic surgical procedure includes Total Hip Arthroplasty: Lateral/Supine.

The equipment is intended for use by trained surgeons in operating theaters.

Comparison of Technological Characteristics:

The substantial equivalence of the Naviswiss Hip Navigation System to the predicate is shown by similarity in intended use, indications for use and performance.

Characteristic	Subject Device	Predicate Device
Device Name	Naviswiss Hip Navigation System	intellijoint HIP Generation 2A System
510(k) #	to be assigned	K162364
Intended use	The Naviswiss Hip Navigation System is a computer-controlled system intended to assist the surgeon in determining reference alignment axes to aid in the positioning of orthopedic implant system components where a reference to a rigid anatomical structure can be identified. The system is only compatible with acetabular cup impactors that have a parallel and straight segment. The system aids the surgeon in performing intra-operative measurements including measurements of leg length, offset, and cup inclination/anteversion. An example of a stereotaxic orthopedic surgical procedure includes Total Hip Arthroplasty: Lateral/Supine. The equipment is intended for use by trained surgeons in operating theaters.	The intellijoint HIP Generation 2A System is a computer-controlled, optical localizer intended to provide intra-operative measurements to a surgeon to aid in selection and positioning of orthopedic implant system components, where a reference to a rigid anatomical structure can be identified. The system is only compatible with straight acetabular cup impactors. The intellijoint HIP Generation 2A System is indicated for patients undergoing orthopaedic surgery, and where the use of stereotactic surgery is considered safe and effective. The system aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning. Example orthopedic surgical procedures include, but are not limited to: Total Hip Arthroplasty Minimally Invasive Hip Arthroplasty
Technology / Scientific principle	Image-free surgical navigation system using infrared stereo camera	Uses infrared optical technology and integrated microelectronics
	Identical to predicate	intellijoint HIP® posterior and anterior applications provide real-time, intraoperative measurements to assist orthopaedic surgeons in accurate implant positioning for cup position, leg length, offset and hip center of rotation.
	Identical to predicate	Measure changes in leg length, offset and hip center, as well as native acetabular position and cup position (anteversion and inclination)

Device Description	Naviswiss Hip Navigation System is an image-free surgical navigation system, consists of a handheld navigation device and a computer module	3D mini-optical navigation system, surgeon controlled surgical guidance tool
Cleaning and Sterilization Shelf-Life	The reprocessing of reusable instruments consists of preparation, precleaning, and automated cleaning followed by sterilization. It was verified that tags are correct after the initial shelf life validation. The navigation unit is draped and used in the sterile area.	The work station is situated outside of the sterile field, in view of the surgeon, while the camera and other equipment remain within the sterile field.
Operating Principle	The M42 employs the base computing, power supply, and programing in the M59 Platform. The NAVItags attach various objects (e.g. the femur, surgical instruments, etc.) for either determining anatomical landmarks or navigating an instrument. The camera utilizes software to guide the surgeon through a workflow process for the surgery.	System generates positional measurements between a camera (mounted on the iliaccrest) and a tracker than can be mounted on various objects (e.g. the femur, the acetabular cup impactor, etc.) during surgery to measure their positions. The camera detects the tracker within its field of view and communicates with a workstation, which executes the application software to guide the device workflow and display measurements to the surgeon.
Performance	All performance tests were passed successfully.	All performance tests were passed successfully.

The technological principle for both the subject and predicate devices is to provide intra-operative measurements during orthopedic surgery. It is based on the use of infrared optical technology to provide real-time, intraoperative data on leg length, offset, and cup position.

The subject and selected predicate devices are based on similar technological elements. The system generates positional measurements between a camera and a tracker that can be mounted on different objects. The camera uses the application software and the tracking software to guide the surgeon through a workflow process for the surgery.

Summary of Testing:

The following tests were performed to demonstrate the substantial equivalence of the Naviswiss Navigation Hip System to the intellijoint HIP Generation 2A System.

Biocompatibility Testing

The biocompatibility evaluation for the Naviswiss Hip Navigation System was conducted in accordance with ISO 10993-1.

Reprocessing Validation

A reprocessing validation was conducted for the reusable instruments.

EMC Testing

Electrical safety and electromagnetic compatibility (EMC) Electrical safety and EMC testing were conducted on the Naviswiss Hip Navigation System. The system complies with the IEC 60601-1, standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted to ensure functional requirements were met and the system performs as intended. Algorithms and measurement calculations were also verified in these tests. All requirements and specifications were met.

System Accuracy

The Naviswiss Hip Navigation System's accuracy was verified according to the methodology in ASTM F2554-18 – Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems. Testing simulated normal conditions, and a variety of worst-case use scenarios and realistic tracking disturbances. All requirements were met.

Benchtop Accuracy

The Naviswiss Hip Navigation System's accuracy was verified using calibrated test fixtures. All requirements were met.

Anatomical Phantom Simulated Use and Clinical Accuracy

Simulated use testing was performed on a metallic bone simulator by orthopedic surgeons in THA procedures following a typical workflow. The test validated that the Naviswiss Hip Navigation System satisfies user needs, intended use, and clinical accuracy requirements. This was assessed by comparing the measurements obtained in the simulated use with known values.

Cadaver Simulated Use

Simulated use testing was performed in multiple cadaver wet labs to validate the Naviswiss Hip Navigation System satisfies clinical use requirements and performed as intended on human specimans when used in an OR environment by trained surgeons.

OUS Prospective Clinical Study

Naviswiss is conducting a prospective clinical study in Australia. The study was designed to evaluate 35 patients undergoing elective THA surgery. The primary outcome is the agreement between intraoperative component positioning data captured by the Naviswiss Hip Navigation System compared with post-operative CT measurements.

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, Naviswiss Hip Navigation System, is substantially equivalent to the legally marketed predicate device, intellijoint HIP Generation 2A System (K162364).