January 31, 2023

Naviswiss AG
% Frederike Bruhschwein-Mandic
Senior Consultant
confinis AG
Hauptstrasse 16
Dudingen, 3186
Switzerland

Re: K223351
Trade/Device Name: Naviswiss Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 2, 2022
Received: November 2, 2022

Dear Frederike Bruhschwein-Mandic:

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 -S

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223351

Device Name
Naviswiss Knee

Indications for Use *(Describe)*
The Naviswiss Knee 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 aids the surgeon in performing intra-operative measurements of femoral and tibial alignment axes to assist in executing the distal femoral and proximal tibial resections. 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.

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

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# 510(k) Summary

Prepared on: 2023-01-31

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
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| Correspondent Contact | Mrs. Frederike Bruhschwein-Mandic |
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## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Naviswiss Knee |
| Common Name | Orthopedic stereotaxic instrument |
| Classification Name | Stereotaxic instrument |
| Regulation Number | 882.4560 |
| Product Code | OLO |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K193094 | Naviswiss Hip | OLO |
| K191507 | Intellijoint Navigation System | OLO |

## Device Description Summary

21 CFR 807.92(a)(4)

The Naviswiss Knee is a surgical navigation system which assists the orthopaedic surgeon during the implantation of an artificial knee joint. It consists of a navigation unit which is first used to register the patient's anatomy. Subsequently the navigation system supports the surgeon in guiding the surgical instruments with the goal to position the implant according to the pre-operative planning.
The navigation unit includes an infrared stereo camera which measures the position and orientation of small NAVItags.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Naviswiss Knee 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 aids the surgeon in performing intra-operative measurements of femoral and tibial alignment axes to assist in executing the distal femoral and proximal tibial resections. The equipment is intended for use by trained surgeons in operating theaters.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are similar in comparison to the primary predicate.

## Technological Comparison 21 CFR 807.92(a)(6)

The Naviswiss Knee is using the same principle of operation compared to the primary predicate and the reference device: using image-free surgical navigation with a camera and either NAVItags for the Naviswiss devices or Bone Tracker for the reference device.
The accuracy of measurement is as accuracte as the primary predicate Naviswiss Hip.
The possibility of a connection to an external monitor via a Wifi module to display the same information as on the navigation unit has been introduced to the Naviswiss Knee. In addition, a tablet can now be used with the Naviswiss Knee to display the same information as on the navigation unit.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Benchtop Accuracy

The Naviswiss Knee'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 Knee 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 Knee
Navigation System satisfies clinical use requirements and performed as intended on human specimans when used in an OR environment by trained surgeons.

Clinical Testing

Not Applicable.

The testing demonstrated that the Naviswiss Knee is substantially equivalent to the legally marketed predicate devices for its intended use.