March 8, 2023

PathKeeper Surgical LTD
Erez Lampert
CEO
Hatachana 1, Migdal Menivim floor 1 , Spaces.
Kfar-Saba,
Israel

Re: K222355
Trade/Device Name: PathKeeper System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 3, 2023
Received: February 6, 2023

Dear Erez Lampert:

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,

Jesse Muir -S

For: 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)*
K222355

Device Name
PathKeeper System

Indications for Use *(Describe)*
The PathKeeper System is a stereotaxic image guidance system intended for the spatial positioning and orientation of surgical instruments used by orthopedic surgeons and neurosurgeons during posterior approach spinal fusion surgeries when pre-operative CT imagery is available. The System, with PathKeeper spine surgery planning and navigation software and 3D optical camera, is intended as an aid for precisely locating anatomical structures in posterior approach open spine fusion surgery during pedicle screw placement in the thoraco-lumbo-sacral region.

The device is indicated for posterior approach open spine fusion surgery during pedicle screw placement in the thoraco-lumbo-sacral region where reference to a rigid anatomical structure can be identified.

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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**510K Summary as Required by 21 CFR 807.92**

**510(k) Summary**
**K222355**

## 1. SUBMITTER'S INFORMATION


**Submitter Name:** PathKeeper Surgical LTD.

**Establishment Registration Number**: Applying

**Address**: Hatachana 1 Kfar-Saba ,Migdal Menivim floor 1 , Spaces., Israel

**Post Code**: 4453001

**Phone: +972523233038**

**Application Correspondent**

**Contact Person**: Erez Lampert

**Email**: erez.lampert@path-keeper.com


Date prepared: 04-March-2023

## 2. SUBJECT DEVICE INFORMATION

| | |
|---|---|
| **Type of 510(k) :** | Traditional |
| **Device Name** | PathKeeper System |
| **Device Common Name** | Computer-assisted surgical device |
| **Device Classification Name** | Orthopedic Stereotaxic Instrument |
| **Review Panel** | Orthopedic |
| **Product Code** | OLO |
| **Regulation Number** | 21 CFR 882.4560 |
| **Regulatory Class** | II |
| **Regulation Medical Specialty** | Neurology |

## 3. PREDICATE DEVICE INFORMATION

| | |
|---|---|
| **Sponsor** | 7D Surgical Inc. |
| **Device Name and Model** | Envision 3D™: Image Guidance System |
| **510(k) Number** | K162375 |
| **Product Code** | OLO |
| **Regulation Number** | 21 CFR 882.4560 |
| **Regulation Class** | Class II |

No reference devices were used in this submission.

## 4. DEVICE DESCRIPTION

The PathKeeper System is an Orthopedic Surgical Navigation System. The system provides registration between preoperative computed tomography (CT) data and intraoperative Optical Topographic Image (OTI) data acquired using a proprietary OTI 3D camera. The system provides surgical guidance data by displaying the location of optically tracked Surgical Accessories relative to the patient anatomy, based on the calculated registration. Position and orientation data of PathKeeper's Tracked Surgical Accessories are linked to the preoperative scan data using the workstation.

The PathKeeper System is designed for open spine surgery where reference to a rigid structure – Dynamic Reference Frame (DRF) – spine reference DRF – can be identified relative to the pre-operative image data of the anatomy. In open spine surgery the posterior elements of the operated vertebrae are exposed, either unilaterally or bilaterally. PathKeeper System's 3D image-processing capabilities provide co-registration of the topography of exposed bone structures obtained by the proprietary OTI 3D camera, to the pre-operative CT scan of the patient.

The PathKeeper System is a portable console.

The components of the PathKeeper System are, in arbitrary order:

- **Workstation Cart with Articulated Arm ALSO referred to as Cart with Head (articulated arm and Camera) –** A high-resolution proprietary Camera with OTI capabilities mounted to an articulated rigid metallic holding arm, computer (with PathKeeper software installed), monitor, keyboard, mouse, and DVD drive on a medical-grade cart. The cart with its parts described above, is provided nonsterile with cleaning instructions in the User Manual. There is no patient contact.

- **PathKeeper Software** for pre-operative planning and intra-operative registration and navigation. The PathKeeper Software shall be installed on the workstation computer and displayed on the workstation monitor and will perform the bulk of the required computation for the system to operate. There is no patient contact.

- **Surgical Accessories Kit** including the following components**:**

  - 6 Navigation Dynamic Reference Frames (DRFs) which are to be attached to common surgical tools (i.e., Awl, Pedicle probe, and Screwdriver). **Note:** Tools are not provided with the system and are not subject to this submission

  - Tool setup/calibration plate DRF

  - Spine reference DRF

- Sterilization case (all DRFs above reside in this case)

These tools are reusable, steam-sterilized accessories serving as spatial markers.

- **Spheres -** Single-use sterile standard navigation Retro-Reflective Spheres. **Note:** these are acquired off-the-shelf items and not provided with the system or the subject of this submission.

- **Patient reference attachment mechanism** – off-the-shelf attachment mechanism (Walton Cartilage Clamp, 8", Curved, Catalog # 270-170, manufactured by Integra LifeSciences) via which the Spine reference DRF (patient reference) is connected to the bony anatomy of the spine. **Note:** this is an acquired off-the-shelf item and not provided with the system or the subject of this submission.

- **Sterile cover for handle** – off-the-shelf single-use sterile cover (Universal Surgical Light Handle Cover, Catalog # LB82, manufactured by Steris Corporation) same as for OR lighting handles. **Note:** this is an off-the-shelf item and not provided with the system or the subject of this submission.

**The Workstation Cart** serves the following purposes:

- Easy movement of system with secure attachment of all moveable components to the cart.
- Space efficient storage of system, when not used.
- Allow stable positioning of the entire system when in use. Safe enclosure of the computer and electric supplies.
- Allow user interaction and data-transfer to and from the computer workstation.

**The Articulated Arm** of the system serves the following purposes:

- Link the cart and the head allowing easy positioning of the head by the sterile surgeon but is stable otherwise (no motion of the head after positioning).
- Allow positioning of the head outside of the sterile field in all positions
- Provides mechanisms for routing cables between the head and the cart.

**The Head** (the Articulated Arm and Camera) of the system serves 2 main purposes:

- Capture 3D images of the intraoperative patient anatomy to facilitate registration of patient preoperative data with the local surgical coordinate system to enable surgical navigation.
- To passively track the location of the PathKeeper Tracked Surgical Accessories tools within the surgical field and provide intraoperative guidance to the surgeon.

**The Software** links all system components and displays navigational data to the surgeon. It provides methods for loading preoperative scans and guides the surgeon through the process of surface model creation, 3D image acquisition, registration, registration verification and navigation.

**The Surgical Accessories Kit serves the following purposes:**

- Enables the surgeon to view the position and orientation of PathKeeper-Tracked Surgical Accessory tools relative to registered pre-operative image data while performing the surgical procedure.
- An aid for precisely locating anatomical structures in both neurosurgical and orthopedic procedures.

PathKeeper Tracked Surgical Accessory is a DRF (Dynamic Reference Frame) attached to a standard surgical tool (not provided). Each DRF utilizes 4 commercially available passive reflective marker spheres [Manufactured by IZI MEDICAL, INC.; 510(k) K022074] used to determine the position and orientation of each PathKeeper's Tracked Surgical Accessory. Each DRF requires a unique marker position configuration to enable the tracking system to distinguish the Accessories from one to the other.

## 5. INTENDED USE/INDICATION FOR USE

The PathKeeper System is a stereotaxic image guidance system intended for the spatial positioning and orientation of surgical instruments used by orthopedic surgeons and neurosurgeons during posterior approach spinal fusion surgeries when pre-operative CT imagery is available. The System, with Pathkeeper spine surgery planning and navigation software and 3D optical camera, is intended as an aid for precisely locating anatomical structures in posterior approach open spine fusion surgery during pedicle screw placement in the thoraco-lumbo-sacral region.

The device is indicated for posterior approach open spine fusion surgery during pedicle screw placement in the thoraco-lumbo-sacral region where reference to a rigid anatomical structure can be identified.

## 6. COMPARISON OF INTENDED USE / TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

PathKeeper System and predicate has similar indications for use.

PathKeeper System and predicate have similar primary intended uses. Predicate has additional intended use of surgical luminaire during image guided surgery. The PathKeeper System does not require additional luminaire, other than existing luminaire in operation room during image guided surgery, and its camera is fit for the existing lighting conditions. Hence, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

Tracking navigation with 3D structured light images is the technological principle for both the subject and predicate devices. It is based on the use of 3D camera, tracking tools made of DRF (Dynamic Reference Frame) with reflective spheres and dedicated software. Enabling surgical guidance data by displaying the position and orientation of tools relative to patient

anatomy.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Use of Structured Light illumination for optical 3D surface reconstruction
- Use of wireless DRF to track navigation tool and spine position.
- Software enabling tracking, planning, registration, calibration, verification of registration and calibration, navigation.

The following technological differences exist between the subject and predicate devices:

- Surgical light - Predicate incorporates extra surgical light since the navigated parts of the procedure prevent the acquisition of structured light images due to saturation of cameras from OR lighting. The PathKeeper System does not require additional lighting. The PathKeeper System camera uses Near Infrared (NIR) spectrum and not visible light for structured light illumination and image capture. The OR light does not saturate the camera. Therefore, the lack of illumination module does not raise additional questions of safety or performance.

- Navigation Tracking tool Assembly – The 7D Tracked Navigation Tool is a one-piece instrument (DRF with surgical tool), whereas PathKeeper's Tracked Surgical Accessory tool is a similar instrument comprised of a DRF (Dynamic Reference Frame) that is to be attached to a standard surgical tool (not provided) before surgery. Both tracking tools are made of similar stainless steel and biocompatible material. Attaching DRF to surgical tool is done by sterile nurse/surgeon prior to surgery. Failing to securely attach DRF to surgery tool is recognized by software at tool calibration phase. From the stage that DRF is attached to surgical tool, the mode of operation is the same. Predicate's tool and Pathkeeper Surgical's tool are neurosurgical and orthopedic instruments with spatial positioning and orientation capabilities. Hence, navigation tracking tool raises no new concerns of safety or performance.

## 7. SAFETY CONSIDERATION

Electrical safety and EMC testing were conducted on PathKeeper System. The device complies with recognized electrical safety standards: ANSI AAMI IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for electromagnetic compatibility.

The biocompatibility evaluation for PathKeeper System was conducted in accordance with the FDA Guidance use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" of September 4th 2020 , International Standard ISO 10993-1 :2018 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process" and ISO 14971:2019 "Medical devices — Application of risk management to medical devices" as recognized by FDA.

Given its characteristics, PathKeeper Surgical Accessories Kit is categorized per Annex A of ISO 10993-1 as follows: Externally communicating medical device in limited contact with tissue, bone, dentin. The evaluation and test reveal that biocompatibility requirements are met.

## 8. NON-CLINICAL PERFORMANCE DATA

The following performance data were provided in support of the safety and effectiveness of the PathKeeper System:

- Non-Clinical System, Software, and Instrumentation Verification and Validation
- Non-Clinical Performance Surgical Simulations Conducted on Phantom Models
- Surgeon Performed Human Cadaveric Workflow Study – from usability testing
- Non-Clinical Human Cadaver Performance Testing
- Non-Clinical Performance Registration Testing
- Cadaveric Porcine Study Performed on Reference Frame Clamp Stability
- Compliance Conformity Assessments:
  - ANSI AAMI IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  - IEC 60825-1 Safety of laser products - Part 1: Equipment classification, and requirements
  - IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
  - IEC 60601-1-6 Medical Electrical Equipment - Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability
  - ISO 10993-1Biological evaluation of medical devices.
  - ISO TS 17665 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1
  - ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities with 4 Amendments
  - ASTM F2554-18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

The performance tests verify and assure of the device's accuracy, repeated accuracy and navigation accuracy according to ASTM F2554-18. Also, Target Registration Error results were calculated assessing clinical accuracy of system comparing to ground truth position (on phantom) in simulated conditions.

The following Table summarizes Verification and Validation activities performed on the PathKeeper System:

| **Verification and Validation** | **Description** | **Conclusion** |
|---|---|---|
| System Verification | Scope of the test is to verify the design requirement specifications of the PathKeeper System under test case protocols. | Verification successful if all design requirements have been fulfilled |

| Verification and Validation | Description | Conclusion |
|---|---|---|
| System Validation | Scope of the test is to validate the Indications for Use and Customer Requirements of the Path keeper System under simulated use case situations. | Validation successful if all user needs met. |
| Usability | This test is conducted to validate the PathKeeper System with respect to user errors. | Validation successful if device is safe and effective with respect to user errors. |
| Safety regarding risk analysis | Implementation and effectiveness of all risk control requirements specified in the PathKeeper System risk analysis are tested and verified. | Risk Control requirements are effective and mitigate the associated risks to an acceptable level. |
| Product Safety standards | The PathKeeper System tested according to the recognized standards listed in the table below (Table 6) including ANSI AAMI 60601-1, IEC 60601-1-2, IEC 60601-1-6, ISO 10993-1. IEC 60825-1 and ISO TS 17665 | Compliance with recognized standards have been verified. |
| Non- Clinical Accuracy | The system was tested on phantom models following ASTM F2554-18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems, in addition to Target Error Registration. Non-Clinical Human Cadaver Performance Testing and Performance Registration Testing were also performed. | All accuracy specification were met |

Verification and validation activities were conducted and confirmed that our device meets the performance and safety requirements under its indication for use condition.

## 9. CLINICAL DATA

Clinical data was not required to demonstrate safety and effectiveness of the PathKeeper System. Clinical validation is unnecessary as the PathKeeper System introduces no new indication for use device features are equivalent to previously cleared predicate device identified.

The clinical safety and effectiveness of Image guided surgery systems are historically accepted for both predicate and subject device.

## 10. FINAL CONCLUSION

The PathKeeper System is substantially equivalent in safety and effectiveness to the predicate devices identified above:

- The predicate devices and PathKeeper System use similar technologies.
- The predicate devices and PathKeeper System both conform to similar electrical and physical safety standards.

The conclusions drawn from the non-clinical tests demonstrate that the PathKeeper System, performs as safely and effectively as the legally marketed device according to the comparison based on the requirements of 21 CFR §882.4560 and the information provided herein, it is concluded that the PathKeeper System is substantially equivalent to the predicate device with respect to its indications for use, technological characteristics, and performance characteristics.