



October 10, 2023

ISYS Medizintechnik GMBH  
% Pedro Costa  
Bergwerksweg 21, Salzburg  
Kitzbuehel, AT 6370  
AUSTRIA

Re: K230130  
Trade/Device Name: Micromate™ Navi+  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed Tomography X-Ray System  
Regulatory Class: Class II  
Product Code: JAK  
Dated: September 8, 2023  
Received: September 8, 2023

Dear Pedro Costa:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A stylized signature of "Lu Jiang" in a cursive font, overlaid on a large, light blue "FDA" logo.

Lu Jiang, Ph. D.  
Assistant Director  
Diagnostic X-Ray Systems Team  
DHT8B: Division of Radiologic Imaging  
Devices and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K230130

Device Name

Micromate™ Navi+

Indications for Use (Describe)

The Micromate™ Navi+ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the user in the positioning of 8–19 gauge needles in the chest, abdomen and musculoskeletal structures when computed tomography (CT) optical navigation can be used for target trajectory planning and intra-operative tracking. The needle is then manually advanced by the user. Trajectory planning is made with software that is a part of the Micromate™ Navi+ device.

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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## 510(k) Summary (K230130)

1. Applicant: iSYS Medizintechnik GmbH
2. Address: Bergwerksweg 21  
6370 KITZBÜHEL / AUSTRIA
3. Contact Person: Pedro Costa  
Tel. +351 919 073 292 e-mail: [Pedro.Costa@interventional-systems.com](mailto:Pedro.Costa@interventional-systems.com)
4. Preparation Date: December 2022.
5. Trade Name: Micromate™ Navi+
6. Common Name: Robotic Positioning Unit
7. Classification Name: Computed tomography x-ray system  
Product Code JAK, Reg.No. 892.1750
8. Substantial Equivalence: Micromate™ Navi+ is substantially equivalent to the following legally marketed devices:

**Predicate Device:**

Micromate™ (iSYS Medizintechnik GmbH), K203720  
Product Code JAK, Reg. No. 892.1750

**Reference Device:**

Excelsius GPS System (Globus Medical Inc), K171651  
Product Code OLO, Reg. No. 882.4560

9. Purpose  
The purpose of this submission is clearance of Micromate™ Navi+ as a new version of previously cleared Micromate™ (K203720) device that is complemented with additional/changed accessories and components, aimed to improve device performance by supporting and augmenting the already existing features as well as to expand its capabilities to Optical Navigation workflow.  
The characteristics of Micromate™ Navi+ device are equivalent to those of the predicate and/or reference device identified on the comparison table, which is provided with the premarket notification submission. It is our opinion that Micromate™ Navi+ system does not have technological characteristics that raise additional questions related to terms of safety and effectiveness.
10. Device Description: The Micromate™ Navi+ system allows the percutaneous execution of a surgical intervention by providing instrument guidance according to one or more pre-operative plans defined by an internal planning and navigation software (MicroNav). The alignment to the surgical plan is performed through a manual gross-positioning using a Positioning Arm, followed by automatic or joystick-controlled movement with image guidance, such as optical CT navigation (tracked by camera). After alignment, the advancement of surgical instruments and delivery of therapy is performed manually by the user, while the position is retained by the targeting platform of

Micromate™ Navi+, relying on the displayed navigation information or real-time images from third party imaging device.

The Micromate Navi+ device is intended for biopsy and percutaneous tumor ablation procedures, in the abdomen, thorax and musculoskeletal tissue.

The Micromate™ Navi+ system comprises the following main components:

- Targeting Platform, a robotic positioning unit that aligns to the surgical plan and holds the surgical instruments through an end-effector acting as a tool-guide adapter,
- Control Unit, device that allows the automatic or manual control of the Targeting Platform movement and can communicate with an internal planning and navigation station,
- Positioning Arm, a multi-functional arm that is used to gross-position the Targeting Platform in such a way the trajectory is reachable,
- Strain Relief Box, which distributes power and data through the Micromate™ system,
- Power and Network Unit, which connects the system to power and allows an optional direct point-to-point connection to an internal planning and navigation station for input of real-time navigation data,
- Connecting Cables.

and following Accessories:

- Sterile Drapes for the Control Unit and Targeting Platform,
- Needle guides for instrument guidance, packaged together with a drape for the sterile covering of the Targeting Platform,
- Sterile Tracker, to which off-the-shelf mounting spheres can be attached, to enable optical tracking for the localization of the Targeting Platform in space,
- A trolley for transport and storage,
- Medical grade PC,
- Camera tracking system,
- Planning and navigation software (MicroNav).

For listed accessories following table is the proposal of classification according to Title 21 of the Code of Federal Regulations (CFR), Parts 862-892:

Accessory:	Is intended for use with one or more parent devices?	Is intended to support, supplement, and/or augment the performance of one or more parent devices?	Proposed accessory classification	Comment
MicroNav (planning and navigation software)	Yes, according to MicroNav intended use: The MicroNav is intended to support the alignment of an external targeting platform (such as Micromate™) to a plan defined pre- or intra-operatively by the user, in image-guided procedures.		Inclusion in the same classification as the parent device. Regulation No. 892.1750 System, X-ray, Tomography, computed. Product Code: JAK Class II	
Medical grade PC	Yes, Cybermed S24 Medical grade PC is intended to support Micromate™ by providing PC hardware environment for proper operation of MicroNav software and necessary communication/data transfer to other accessories or components of the system, temporary storage of provided data, conversion, and display of provided DICOM images. Intended use: CyberMed S series products are designed for general pc application in the health care environment. It can be used for Radiology, PACS (Picture Archiving Communication Systems), LIS (Lab Information Systems), COW (Computer on Wheels), and Electronic Medical Record purposes. It shall not be used for life-supporting systems.		Inclusion in the same classification as the parent device. Regulation No. 892.1750 System, X-ray, Tomography, computed Product Code JAK Class II	Medical grade PC used as component in already 510(k) cleared device Device name: Practical Navigation Surgical Guidance System (PNSGS) Applicant: Practical Navigation, LLC (K202184)
Atracsys camera	Yes, the SpryTrack sTk180 Optical Tracking System is a flexible, real-time tracking technology based on a stereo camera approach intended to support and augment Micromate™ during the navigated workflow procedure.		Inclusion in the same classification as the parent device. Regulation No. 892.1750 System, X-ray, Tomography, computed Product Code JAK Class II	/
Trolley (Supplier: iTD GmbH)	Yes: Third party trolley manufactured by ITD GmbH (FDA registration number 3007713438). The uni-cart single-column cart is small, manoeuvrable and ideal for space-saving, mobile use. It offers a high degree of stability for the integration of small medical devices and monitors for patient monitoring intended to support Micromate™ by providing a platform for storage and transport of device components and accessories.		FDA listed device: Device name: Uni-cart Registered Establishment Name: ITD GMBH Regulation No. 868.6175 Class I 510(k) exempt	/
Optical tracker	Yes, according to intended use: Optical tracker is a rigid frame intended to provide necessary position in space of tracking spheres in accordance to Micromate end-effector.		Already 510(k) cleared: EXACT MEDICAL MANUFACTURING, INC (K101689)	/
Tracking spheres	Yes, disposable Tracking spheres is intended to be used for patient referencing and tool registration in image guided surgeries. Indications for use: For use as a stereotactic system accessory to aid in auto-registration and localization of rigid patient anatomical structures in either open or percutaneous image guided surgery. It is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure can be identified relative to a CT or MR-based model of the anatomy.		Already 510(k) cleared: I.Z.I. CORP. (K022074)	/

The system can be mounted to different bed/table through a specific adapter for each type of table. Third-party sterile instruments, tool guides and optical tracker (with spheres) are connected over the sterile drape to the Targeting Platform end-effector.

Micromate™ Navi+ is not patient contacting.

11. Intended Use: The intended use of the Micromate™ Navi+ device is to function as a remote-operated positioning and guidance system for needle placement during interventional procedures. Positioning is done in a remote-controlled manner; planning of the position/angulation is done based on 2D/3D patient data (CT) using an internal image-guided planning and navigation system.

The verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of external imaging devices. The Micromate™ Navi+ system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like- through a third-party needle guide, manufactured by Exact Medical Manufacturing Inc. (K101689): P/N E2178 (Micromate Needle Guide, 8-11G), P/N E2183 (Micromate Needle Guide, 10-14G) and P/N E2184 (Micromate Needle Guide, 15-21G). During operation, the device is covered with a sterile drape, which is part of the P/N2178, P/N E2183 and E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact Medical Manufacturing Inc. (K101689): P/N 11718EU (Micromate Control Unit Drape), tracker frame P/N: E6842, and tracker spheres P/N: 2010 (K022074).

Micromate Navi+ is Intended only for adult use.

12. Indications for use: The Micromate™ Navi+ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the user in the positioning of 8–19 gauge needles in the chest, abdomen and musculoskeletal structures when computed tomography (CT) optical navigation can be used for target trajectory planning and intra-operative tracking. The needle is then manually advanced by the user. Trajectory planning is made with software that is a part of the Micromate™ Navi+ device.

13. Clinical use

#### **Preparing the system:**

After bringing sterile disposables into the operating room, bring the Micromate™ to the vicinity of the operating table, outside of the sterile field. Position the image-guided panning and navigation station. Prepare the patient according to hospital procedure by placing it in the appropriate position on the OR table.

- Mounting the system on OR environment

- The Targeting Platform is affixed to the OR Table using a multi-functional mechanical support arm, ensuring that the Targeting Platform has sufficient range of motion to be placed over the surgical site
- Inserting the adequate end-effector type as per selected workflow in predicted slot on targeting platform
- Connecting cables between system components
- Draping the system with third-party sterile drape cover (sterile barrier to isolate non-sterile system components)
- The compact tracking Camera is rigidly affixed to the OR table using a multifunctional mechanical support arm in the appropriate position to track the surgical site (option for navigated workflow)
- Perform image recording according to CT navigation workflow. On an external CT system perform a volume scan.
- Bring the targeting platform to HOME position.

#### **CT Navigated workflow:**

##### Prerequisites:

- The tracker camera is mounted.
- Tracker with tracking spheres is mounted on the Micromate Targeting Platform end effector
- Both positioning arms, for camera and Micromate Targeting Platform are locked.

##### Workflow steps:

- Load the study (image data) into a planning and navigation station from a PACS query, direct Communication with the CT or by data on USB flash drive
- The software detects the position of the targeting platform in medical images, in relation to the surgical anatomy based on fiducial markers on the targeting platform
- The system optically tracks its position in real-time, using a peripheral tracking camera, and transmits that information to the software
- Confirmation of the valid RMS registration assessment (green mark) is done by navigation station for both for the Camera and for the Tracker
- Select the instrument type and size and confirm
- Define single plan or multiple plans of intervention
- Perform the gross-positioning of targeting platform by adjusting the positioning arm
- Using the available tools on the external modality, check validity of the trajectory (entry and target point) and confirm
- Perform the intervention (manual insertion of guided instrument performed by the user).

14. **Biocompatibility**      The Micromate™ Navi+ is not in contact with the patient. At any time, when in use, a third-party sterile drape is to be placed between the patient and the system. No biocompatibility studies were considered necessary for this device.

## Device comparison summary

Reference	Micromate™ (predicate device) K203720	Micromate™ Navi+ (subject device) K230130	Excelsius GPS (reference device) K171651
<b>510(k) Number</b>	K203720	K230130	K171651
<b>Manufacturer</b>	iSYS Medizintechnik GmbH Bergwerksweg 21 6370 Kitzbühel Austria	iSYS Medizintechnik GmbH Bergwerksweg 21 6370 Kitzbühel Austria	Globus Medical Inc. 2560 General Armistead Ave. Audubon, PA 19403 610-930-1800
<b>DESIGN</b>			
<b>General Device Description</b>	<p>Computer controlled electromechanical multi-jointed arm indicated for both stereotactic and non-stereotactic invasive procedures.</p> <p>The Micromate™ system allows the percutaneous execution of a surgical intervention by providing instrument guidance according to one or more pre-operative plans defined in an external planning or navigation station. The alignment to the surgical plan is performed through a manual gross positioning using a Positioning Arm, followed by automatic or joystick-controlled movement with image guidance, such as CT and fluoroscopic image.</p>	<p>Computer controlled electromechanical multi-jointed arm indicated for both stereotactic and non-stereotactic invasive procedures.</p> <p>The Micromate™ Navi+ system allows the percutaneous execution of a surgical intervention by providing instrument guidance according to one or more pre-operative plans defined in planning or navigation station.</p> <p>The alignment to the surgical plan is performed through a manual gross positioning using a Positioning Arm, followed by automatic or joystick-controlled movement with image guidance, such as CT.</p>	<p>The EXCELSIUS GPS™ is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera</p>
<b>Localization Method</b>	Optical system (infrared camera)	Optical system (infrared camera)	Optical system (infrared camera)
<b>Planning software</b>	Third-party	Yes (MicroNav)	Yes (EXCELSIUS™ GPS Planning and Navigation Application software)
<b>Registration method</b>	By navigation/imaging software during intervention	By navigation/imaging software during intervention. Registration fixture during 3D intraoperative images is part of the Targeting Platform's end-effector.	Registration fixture during 3D intraoperative images. Fluoroscopic merge to pre-op CT Registration fixture in place during fluoroscopy
<b>Instrumentation</b>	Tool Guides P/N: 11718EU (Sterile Drapes Manufacturer: Exact MM (K101689), P/N E2178 (Micromate Needle Guide Set, 8-11G), P/N E2183 (Micromate Needle Guide Set, 10-14G) and P/N E2184 (Micromate Needle Guide Set, 15-21G). During operation, the device is covered with a sterile drape, which is part of the P/N2178, P/N E2183 and E2184. An additional third-party Control Unit Drape is available,	Tool Guides P/N: 11718EU (Sterile Drapes Manufacturer: Exact Medical Manufacturing Inc. (K101689), P/N E2178 (Micromate Needle Guide, 8-11G), P/N E2183 (Micromate Needle Guide, 10-14G) and P/N E2184 (Micromate Needle Guide, 15-21G). During operation, the device is covered with a sterile drape, which is part of the P/N2178, P/N E2183 and E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact Medical	N/A

	also manufactured by Exact MM (K101689): P/N 11718EU (Micromate Control Unit Drape	Manufacturing Inc. (K101689): P/N 11718EU (Micromate Control Unit Drape	
<b>Instrument Fixation and Instrument Guide Position Adjustment</b>	Special tool holders for different applications mounted to the device Trajectory and location set by the robot. Instruments are manually positioned by the user through the needle guides on the robotic arm.	Special tool holders for different applications mounted to the device Trajectory and location set by the robot. Instruments are manually positioned by the user through the needle guides on the robotic arm.	Trajectory and location set by the robotic arm. Instruments are manually positioned by the user through the Guide Tube on the robotic arm.
<b>System Operation</b>			
<b>Principles of operation</b>	Positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used to hold and guide standard instruments, based on a pre-operative, operative (real time) plan or feedback from an image-guided navigation system or trajectory planning station with two-dimensional or three-dimensional imaging software. • Provide a mechanical connection to positioning devices on interventional tables. • Align to an active surgical plan in a planning or navigation system. • Provide manual or automatic motion control. • Support the insertion and release of instrumentation, through an accessory end-effector.	Positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used to hold and guide standard instruments, based on a pre-operative, operative (real time) plan or feedback from an image-guided navigation system or trajectory planning station with two-dimensional or three-dimensional imaging software. • Provide a mechanical connection to positioning devices on interventional tables. • Align to an active surgical plan in a planning or navigation system. • Provide manual or automatic motion control. • Support the insertion and release of instrumentation, through an accessory end-effector.	Intraoperative preoperative images Patient registration Surgical planning Real-time tracking of navigated instruments Guidance of instruments
<b>Input Images</b>	N/A	3D Pre-operative images 3D Intraoperative images 2D Intraoperative images	3D Pre-operative images 3D Intraoperative images 2D Intraoperative images
<b>Trajectory planning parameters</b>	N/A	Entry point, target point, length of the trajectory, diameter of the instrument	Entry point, target point, length of the instrument, diameter
<b>Camera system</b>	N/A	Stereo	Stereo
<b>Image-guided</b>	YES	YES	YES
<b>Accuracy verification landmarks</b>	N/A	YES (Scout scans, live fluoroscopy imaging, or acquisition of a new volume scan for re-registration)	YES (Landmark anatomical array)
<b>Accuracy Verification</b>	Yes (performed by user)	Yes (performed by user)	Yes
<b>Intended Use</b>	The intended use of the Micromate™ device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in a remote controlled manner; planning of the position/angulation is done based on 2D/3D patient data	The intended use of the Micromate™ Navi+ device is to function as a remote-operated positioning and guidance system for needle placement during interventional procedures. Positioning is done in a remote-controlled manner; planning of the position/angulation is done based on 2D/3D patient data (CT) using an	N/A

	<p>(CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device.</p> <p>Also, verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The Micromate™ system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like- through a third-party needle guide, manufactured by Exact MM (K101689): P/N E2178 (Micromate Needle Guide Set, 8-11G), P/N E2183 (Micromate Needle Guide Set, 10-14G) and P/N E2184 (Micromate Needle Guide Set, 15-21G). During operation, the device is covered with a sterile drape, which is part of the P/N2178, P/N E2183 and E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact MM (K101689): P/N 11718EU (Micromate Control Unit Drape).</p> <p>Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.</p>	<p>internal image-guided planning and navigation system.</p> <p>The verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of external imaging devices. The Micromate™ Navi+ system is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like- through a third-party needle guide, manufactured by Exact Medical Manufacturing Inc. (K101689): P/N E2178 (Micromate Needle Guide, 8-11G), P/N E2183 (Micromate Needle Guide, 10-14G) and P/N E2184 (Micromate Needle Guide, 15-21G). During operation, the device is covered with a sterile drape, which is part of the P/N2178, P/N E2183 and E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact Medical Manufacturing Inc. (K101689): P/N 11718EU (Micromate Control Unit Drape), tracker frame P/N: E6842, and tracker spheres P/N: 2010 (K022074).</p> <p>Micromate Navi+ is Intended only for adult use.</p>	
<b>Indications for Use</b>	<p>The Micromate™ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the user in the positioning of a needle or instrument where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the user. Trajectory planning is made with software that is not part of the Micromate™ device.</p>	<p>The Micromate™ Navi+ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the user in the positioning of 8–19 gauge needles in the chest, abdomen and musculoskeletal structures when computed tomography (CT) optical navigation can be used for target trajectory planning and intra-operative tracking. The needle is then manually advanced by the user. Trajectory planning is made with software that is a part of the Micromate™ Navi+ device.</p>	<p>The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or Guide Tube to be used by users for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.</p>
<b>Anatomical site</b>	Total body	Total body	The system is indicated for the placement of spinal and orthopedic bone screws.
<b>User</b>	Physician	Physician	N/A

<b>Real-time instrument position</b>	Yes (on third-party planning or navigation station, or on imaging device)	Yes (on planning or navigation station, or on imaging device)	Yes
<b>Technology</b>			
<b>Powered</b>	Yes	Yes	Yes
<b>CE-Conformity</b>	Yes	Yes	Yes
<b>Computer-controlled</b>	Yes	Yes	Yes
<b>Materials</b>	Metal, electronics and plastics	Metal, electronics and plastics	N/A

### Similarities and Differences:

The Micromate™ system is the second generation robotic platform of iSYS Medizintechnik GmbH and Micromate™ Navi+ is an evolution of Micromate™, preserving the intended use and indications for use, with a changed system architecture and intervention planning input, further expanding available features and workflow set equivalent to suggested FDA cleared devices. Details of equivalence are presented in the device comparison table.

The Micromate™ Navi+ system and the Micromate™ have same indications and the same intended use, the hardware and firmware design of the control unit and targeting platform is the same, whereas Micromate™ Navi+ system comprises of additional/changed accessories internal planning software, trolley, and third-party external accessories: medical PC, camera and the necessary table/bed adapters are also different. Expanding features are supported by additional positioning arm for camera.

The following list identifies the similarities and differences between the devices.

Micromate™ Navi+ is equivalent to:

1. Micromate™ for having the same general intended use. The intended use of the Micromate Navi+ is a subset of Micromate™ intended use. The Micromate™ Navi+ is therefore equivalent to predicate in this respect within its indications for use
2. Micromate™ for having the same principle of operation
3. Micromate™ robot execution system which is built according to the exact same core system architecture and same hardware design for Control unit and Targeting Platform
4. Micromate™ system for having the same operating principle by allowing an alignment to a surgical plan, thus assisting in the spatial positioning, orientation and guidance of a surgical tool.
5. Micromate™ system for supporting manual and automatic robotic movements.
6. Micromate™ system for having the user verifying the final accuracy
7. Micromate™ system for having the same instrument fixation means
8. Micromate™ and Excelsius GPS system for being image-guided robotic systems
9. Micromate™ and Excelsius GPS system for providing registration means for the imaging device
10. Micromate™ and Excelsius GPS system for having tool guides as instrumentation
11. Micromate™ and Excelsius GPS system for performing of automatic registration of observed objects
12. Micromate™ and Excelsius GPS system for having the final instrument guidance being performed by the physician.

13. Excelsius GPS for having the similar planning and navigation software capable of visualizing acquired radiological images (2D, 3D) and interventional plan created by user, and navigating the system during the execution of previously created plan
14. Excelsius GPS system for having real-time position information provided by a planning software
15. Excelsius GPS system for having equivalent trajectory planning parameters
16. Excelsius GPS for having possibilities for camera (optical) tracking of guided instruments

Differences:

1. Excelsius GPS for registration approach, while keeping the same basic principle of matching patient's anatomy location to location in space of tracking spheres attached to device's end effector.  
Excelsius GPS has patient registration performed by referencing between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy), while Micromate™ Navi+ registration is automatically obtained by triangulation, by comparing the measured positions of the disposable marker spheres (connected to the disposable tracker) in the camera coordinate system, to their pre-specified position in space in relation to the also estimated, position of the subject device end-effector fiducials. This relation allows to calculate the transformation matrix between the camera image space and the subject device image space (which is the CT volume coordinate system).
2. Excelsius GPS for indicated anatomy application. Micromate™ Navi+ is indicated for any image-guided procedure that involves placing or manipulating instruments based on acquired radiology or real time images with, or without, navigation while Excelsius GPS is indicated for placement of spinal and orthopedic bone screws. Although anatomical range of Excelsius GPS is subset of subject device anatomical range, due to general operating principle of locating the target, anatomical structure range is not limiting the reference device equivalence.
3. Excelsius GPS for using dynamic reference frame – Micromate™ Navi+ uses tracker frame attached to the robot's end effector. The use of a dynamic reference frame is state-of-the-art for spine surgery, but depends on the fixation of the frame to a rigid anatomical location, such as bone. In the case of spine surgery, the dynamic reference frame is attached to the spinous process of an adjacent vertebra or other spinal anatomical landmark, as there is a nearly perfect rigid relationship between the structures. That does not hold true for soft tissue and for the relationship between soft tissue and bone. This aspect does not raise additional questions regarding usability or safety. Micromate Navi+'s approach is simpler as it does not require the attachment of another tracked frame and the issues related to frame occlusion and handling. It is also safer, as Micromate Navi+ requires the user to confirm with live imaging or additional scans the position of instruments anytime that is necessary, and especially before the full insertion of the instruments, which is more accurate than relying on tracked data and overlaying navigation data on previously acquired CT scans, which may not reflect the actual location of structures.
4. Excelsius GPS for some additional ergonomic features: Image merging (image fusion) and plan save/load. Micromate™ Navi+ do not have these additional features, but this is not affecting the safety of the workflow neither is reducing the performance.
5. Excelsius GPS for accuracy verification method – Micromate™ Navi+ uses the scout scans instead of pointing a navigated instrument to anatomical location. The user can acquire a new registration scan in case we are inaccurate. The user judges the position of the device itself based on live imaging, or other imaging methods.

## **Non-Clinical Performance Data**

Testing was conducted on the Micromate™ Navi+ system to establish that the system is substantially equivalent to the predicate and reference devices and demonstrate and verify that the device will perform as intended according to the outlined design requirements below:

<b>Description</b>
<b>Safety</b> Verified the effectiveness of all risk controls determined in the device risk analysis. No new issues of safety or effectiveness were raised.
<b>General Requirements and Performance</b> Verified all components against their design specifications. All requirements were met and no new issues of safety or effectiveness were raised.
<b>Electrical Safety and Electromagnetic Compatibility:</b> Testing was performed to assure compliance with recognized safety standards: IEC 60601-1:2005+AMD1:2012 standard for electrical safety and IEC 60601-1-2:2014 standard for electromagnetic compatibility.
<b>Software Verification and Validation Testing:</b> Performed for each requirement specification. Verifying the operating system software requirements are met and software performs as intended. Performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in medical devices, FDA guidance on general principles of software validation and IEC 62304:2006 Medical Device Software – Software life cycle processes.
<b>Hardware Verification testing:</b> Bench testing ensures the hardware requirements identified for the system are met and hardware performs as intended (this includes, but is not limited to, <ul style="list-style-type: none"> <li>• reliability lifetime testing,</li> <li>• functional testing,</li> <li>• performance testing including accuracy</li> </ul>
<b>Usability Engineering:</b> Usability Engineering conducted in accordance with IEC 62366 and FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices” demonstrating that the usability and human factors requirements were adequately met.
<b>Measurement of Positional Accuracy of Computer Assisted Surgical Systems:</b> The navigation accuracy was validated per ASTM F2554-18, and the 95% Confidence Interval (CI) accuracy is also below 2mm and 2° from the trajectory.

### **Accuracy Validation**

The system's bench-test accuracy was validated in a simulated use environment using the claimed compatible instruments and achieved an average accuracy of  $1.04 \pm 0.60\text{mm}$  of lateral deviation and  $0.75 \pm 0.47^\circ$  angular deviation to the planned trajectory, at the instrument tip.

The system's clinical guidance accuracy for the claimed indications was validated in 54 interventions (19 abdominal lesions, 19 thoracic lesions, and 16 musculoskeletal lesions) using the claimed compatible instruments. The system achieved an average clinical guidance accuracy of  $1.48 \pm 1.18\text{mm}$  of lateral deviation and  $1.04 \pm 0.97^\circ$  of angular deviation in abdominal procedures,  $0.62 \pm 0.41\text{mm}$  of lateral deviation and  $0.61 \pm 0.41^\circ$  of angular deviation in musculoskeletal procedures,  $1.76 \pm 1.26\text{mm}$  of lateral deviation and  $1.34 \pm 0.82^\circ$  of angular deviation in thoracic procedures. The overall clinical guidance accuracy in the whole cohort was  $1.33 \pm 1.13\text{mm}$  of lateral deviation and  $1.02 \pm 0.83^\circ$  of angular deviation.

An estimate of the worst-case expectable clinical accuracy was calculated by combining the 99% confidence interval of the clinical guidance accuracy with the 99% confidence interval of the navigation accuracy, as measured per the bench accuracy test. The calculated value was 6.93mm for the abdomen, 4.12mm for the musculoskeletal tissue, 7.41mm for the thorax, and 6.40mm overall, for a needle readjustment rate of  $0.13 \pm 0.45$  times per procedure. The overall scope of accuracy testing supported, with high statistical confidence, a positive conclusion on the safe and effective use of the device in a clinical setting.

### **Statement of safety and effectiveness data**

The Micromate™ Navi+ is substantially equivalent to the legally marketed predicate device. It is our opinion that the subject device system does not have technological characteristics that raise additional questions related to safety and effectiveness.

### **Conclusion**

Micromate™ Navi+ system has been shown through comparison, pre-clinical and performance data gathered in simulated clinical environment, to be substantially equivalent to the identified predicate device. The system claims are a subset of those of the predicate device, for which safety and effectiveness was proven through verification and validation activities, while having the additional technological characteristics and principles of operation equivalent to reference device.

New technological aspects, such as the internal planning and navigation software do not alter the fundamental intended use, indications for use neither the basic operating principle of the device, and do not affect its safety and effectiveness when used as labeled.