ISYS Medizintechnik GMBH
℅ Cornelia Damsky
President
CDI Regulatory Consultants
6552 Hermosa Beach Lane
DELRAY BEACH FL 33446

June 22, 2021

Re: K203720
Trade/Device Name: Micromate™
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 24, 2021
Received: May 26, 2021

Dear Cornelia Damsky:

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)*
K203720

Device Name
Micromate™

Indications for Use *(Describe)*
The Micromate™ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon 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 surgeon. Trajectory planning is made with software that is not part of the Micromate™ 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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005 510(k) Summary

K203720

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbuehel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	January 19, 2021
5.	Trade Name:	Micromate™
6.	Common Name:	Robotic Positioning Unit
7.	Classification Name:	System, X-ray, Tomography, computed Product Code JAK, Reg. No. 892.1750
8.	Substantial Equivalence:	The Micromate™ is substantially equivalent to the following legally marketed devices:

Predicate Device:
iSYS1 (iSYS Medizintechnik GmbH), K131433
Product Code JAK, Reg. No. 892.1750

Reference Device:
Stealth Autoguide™ System (Medtronic Navigation Inc.), K191597
Product Code HAW, Reg. No. 882.4560

The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which is provided with the premarket notification submission. It is our opinion that the Micromate™ system does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.

9.	Device Description:	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. After alignment, the advancement of surgical instruments and delivery of therapy is performed manually by the surgeon, while the position is retained by the system and relying on the displayed navigation information or real-time images.

The 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, a handheld device that allows the automatic or manual control of the Targeting Platform movement and can communicate with an external 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 external planning and navigation station for input of real-time navigation data.
- Sterile Drapes for the Control Unit and Targeting Platform (this one containing also needle guides) for instrument guidance.
- Connecting Cables
- A cart for transport and storage

The system can be mounted to different bed/table through specific adapter accessories and all components are covered with a sterile drape during use. Third-party needle or tool guides are connected to the Targeting Platform end-effector through a customized mechanical interface that preserves the sterile barrier.

Micromate™ is not patient contacting.

10. Intended Use:

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 (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.
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 E2183 (Device Cover with 11G-14G needle guide) or P/N E2184 (Device Cover with 15G-21G needle guide). During operation, the device is covered with a sterile drape, which is part of the P/N E2183 and

E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact MM (K101689): P/N 11718EU (Handheld Device Cover).
Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.

11. Indications for use: The Micromate™ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode 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 surgeon. Trajectory planning is made with software that is not part of the Micromate™ device

12. Clinical Use: Depending on the used operating table, the user selects a specific table adapter and attaches it to the table (a Table Top Adapter for C-arm couchtops, a Standard Baseplate and respective adapters for a CT-table or Fluoro-CT table, Side-Rail Adapters for side-rails on any table). All adapters are equipped with a starburst connector, to which the multi-functional Positioning Arm is connected. The Positioning Arm is equipped with one starburst adapter at the bottom and a spoon adapter at the top, to which the Targeting Platform is connected with a counterpart. A Strain Relief Box (for power distribution and cable management) and the Control Unit for handheld remote control of the Targeting Platform are connected to a side-rail. Both the Targeting Platform and the Control unit are connected to the Strain Relief Box with cables. The Strain Relief Box is then connected to a Power and Network Unit, responsible for the power and data input into the system, respectively through a power cord that is connected to the mains outlet and a network cable that can be plugged into an external planning or navigation station. An end-effector is connected to the Targeting Platform and the assembly (comprised of the Targeting Platform carrying and End-effector and the Positioning Arm) are covered with a sterile drape. A sterile disposable needle guide is connected to the End-effector interface with the sterile drape in place. The Control Unit can optionally be covered with the respective sterile drape. The Targeting Platform is gross-positioning within the region of interest, by locking the Positioning Arm when the Targeting Platform is in the desired position. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning or navigation station. The Targeting Platform is remotely controlled using the Control Unit for fine positioning and to align the needle guide axis to the surgical plan. The surgical instruments are then inserted manually by the user into the needle guide and advanced to the planned target. For procedures requiring the placement of multiple instruments, each instrument can be released from the needle guide after placement and the alignment to additional planned surgical trajectories performed similarly.

13. Biocompatibility: The Micromate™ 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.

14. Performance Data: Operating conditions:
10–30°C (50–86°F), 30-70% RH, non-condensing, 0.689 bar–1.019 bar, altitude up to 3000m (9842 ft).
Shipping conditions:
0–40°C (32–104°F), 20–80% RH, non-condensing, 0.689 bar–1.019 bar.
Storage conditions:
0–30°C (32–86°F), 20–80% RH, non-condensing, 0.689 bar–1.019 bar.
Power supply: 30VA, 100–240 VAC, 50/60 Hz.

Sterilization of the sterile accessories has been validated by Exact Medical Manufacturing (K101689), the legal manufacturer of the sterile drapes and needle guides compatible with the Micromate™.

The accuracy of the intervention is adjunct to the capabilities of the operator and depends on the resolution of the imaging device or software, among other factors. As calculated from actual clinical data, the 95% confidence interval (CI) accuracy of Micromate™ in clinical use is between 0.00 mm to 1.14 mm and 0.25 degrees to 1.70 degrees from the surgical plan. This corresponds to an average accuracy of alignment to the trajectory on Entry Point view of 0.43 ± 0.5mm, and an average angular deviation of the needle when being inserted along the trajectory of 0.79 ± 0.41 degrees. Micromate™ has no influence on the accuracy of the needle placement on target in terms of depth, as the instrument is manually delivered and advanced by the physician, under live imaging. All results were obtained in combination with the Philips Allura Xper FD20 X-ray system.

The mechanical accuracy of the Micromate™ system itself is below 1 mm (relative mechanical accuracy 0.03 mm and absolute mechanical accuracy 0.2 mm), as measured by commanding the Targeting Platform to a predetermined location in air.

Device comparison summary

Reference	iSYS1 (predicate device)	Stealth Autoguide™ System (reference device)	Micromate™ (subject device)	Equivalence?[1]
510(k)-Number	K131433	K191597	K203720	**YES**
Manufacturer	iSYS Medizintechnik GmbH Bergwerksweg 21 6370 Kitzbühel Austria	Medtronic Navigation, Inc. 826 Coal Creek Circle Louisville, Colorado 80027 United States	iSYS Medizintechnik GmbH Bergwerksweg 21 6370 Kitzbühel Austria	-
DESIGN				
General Device Description	Computer controlled electro-mechanical multi-jointed arm indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for use as a stereotactic instrument	Computer controlled electro-mechanical multi-jointed arm indicated for both stereotactic and non-stereotactic invasive procedures	**YES (4)**
Localization Means	Fiducial markers on tool holder	Optical markers on tool holder	Fiducial markers on tool holder	**YES (7)**
Image-guided	Yes	Yes	Yes	**YES (1,3,11)**
Planning software	Third-party	Yes (StealthStation)	Third-party	**YES (1)**
Registration method	By navigation/imaging software during intervention	By navigation/imaging software during intervention	By navigation/imaging software during intervention	**YES (4,7)**
Instrumentation	Marker Tool Holder Sterile Covers (third-party)	Reusable surgical instruments Navigated Trajectory Guide, Tool Holders, Drill Guides, Cranial reducing Tubes, Height Guides and Tapping Tube (K162604)	Tool Guides Sterile Drapes Manufacturer: Exact MM (K101689) Device Cover with 11G-14G needle guide, P/N E2183 Device Cover with 15G-21G needle guide, P/N E2184 Handheld Device Cover, P/N 11718EU	**YES (13)**
Instrument Fixation	Special tool holders for different applications mounted to the device	Special tool holders for different applications mounted to the Stealth Autoguide™	Special tool holders for different applications mounted to the device	**YES (9)**
Instrument Calibration	Intra-operative	Intra-operative	Intra-operative	**YES (8)**
Planning and Navigation Software				
N/A				

[1] The numbers between brackets correspond to the numbered equivalence claims in the section “Similarities and Differences”.

System Operation				
Fiducial markers with registration with pointer probe	No	No	No	**YES (14)**
Optical Registration	No	Yes	No	**Yes (15)**
Ultrasound Registration	No	No	No	**YES (16)**
Accuracy Verification	Yes, performed by user	Yes, performed by user	Yes, performed by user	**YES (17)**
Provide mechanical guidance for tools	Yes	Yes	Yes	**YES (4)**
Instrument Guide Position Adjustment	Robotic movement (manual/joystick or automatic)	Robotic movement (manual/joystick or automatic)	Robotic movement (manual/joystick or automatic)	**YES (4,12)**
Physician carries out final gesture through tool guide	Yes	Yes	Yes	**YES (10)**

Intended Use	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (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. 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 iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc.	The Stealth Autoguide™ System is a positioning and guidance system intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments, based on a pre-operative plan and feedback from an image-guided navigation system with three-dimensional imaging software.	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 (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. 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 E2183 (Device Cover with 11G-14G needle guide) or P/N E2184 (Device Cover with 15G-21G needle guide). During operation, the device is covered with a sterile drape, which is part of the P/N E2183 and E2184. An additional third-party Control Unit Drape is available, also manufactured by Exact MM (K101689): P/N 11718EU (Handheld Device Cover). Applications include, but are not limited to, interventions like biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc..	**YES (2,5)**
Indications for Use	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode 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 surgeon. Trajectory planning is made with software that is not part of the iSYS device.	The Stealth Autoguide™ System is a remotely-operated positioning and guidance system, indicated for any neurological condition in which the use of stereotactic surgery may be appropriate (for example, stereotactic biopsy, stereotactic EEG, laser tissue ablation, etc.).	The Micromate™ device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon 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 surgeon. Trajectory planning is made with software that is not part of the Micromate™ device.	**YES (2,5)**
Anatomical site	Total body	Brain	Total body	**YES (2)**

User	Physician	Neurosurgeon	Physician	**YES (3)**
Accessory	Table Adapters Cable Sets Marker Tool Holder Tool Guides (third party) Sterile Covers (third-party)	Sterile Drapes Head Clamp Adapter Cable Sets Reusable surgical instruments Navigated Trajectory Guide, Tool Holders, Drill Guides, Cranial reducing Tubes, Height Guides and Tapping Tube (K162604)	Table Adapters Cable Sets Marker Tool Holder **Third party accessories** Tool Guides Sterile Drapes Manufacturer: Exact MM (K101689) Device Cover with 11G-14G needle guide, P/N E2183 Device Cover with 15G-21G needle guide, P/N E2184 Handheld Device Cover, P/N 11718EU	**YES (4,6)**
Real-time instrument position	Yes (on third-party planning or navigation station, or on imaging device)	Yes (on StealthStation, using navigation)	Yes (on third-party planning or navigation station, or on imaging device)	**YES (11)**
Mechanical Guidance of Instruments	Yes	Yes	Yes	**YES (4,13)**
Technology				
Powered	Yes	Yes	Yes	**YES (4)**
CE-Conformity	Yes	Yes	Yes	**YES**
Computer-controlled	Yes	Yes	Yes	**YES (4)**
Materials	Metal, electronics and plastics	Metal, electronics and plastics	Metal, electronics and plastics	**YES (4)**

Similarities and Differences:

All three devices are intraoperative instruments used by surgeons for assisting the spatial positioning and orientation of a surgical tool.

The iSYS1 system is the first-generation robotic platform of iSYS Medizintechnik GmbH and Micromate™ is an evolution of iSYS1, preserving the operating principle and the intended use and indications, with a changed system architecture and control mechanism.
Furthermore, although the Micromate™ system and the Stealth Autoguide™ have different indications and a slightly different intended use, the hardware design of the main system components is the same, whereas software and the necessary table/bed adapters is also different.

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

Micromate™ is equivalent to:

1. iSYS1 for having a third-party planning software.
2. iSYS1 for having the same intended use and indications, both in a wider, but compatible field of applications than that of the Stealth Autoguide™.
3. iSYS1 for being used by any trained physician.
4. Stealth Autoguide™ system which is built according to the exact same core system architecture and same hardware design
5. iSYS1 and Stealth Autoguide™ 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.
6. iSYS1 and Stealth Autoguide™ system for having the same type of accessories.
7. iSYS1 and Stealth Autoguide™ system for being localized by an external navigation or imaging software.
8. iSYS1 and Stealth Autoguide™ system for providing registration means for the imaging device and intra-operative calibration on the registration step.
9. iSYS1 and Stealth Autoguide™ system for having the same instrument fixation means.
10. iSYS1 and Stealth Autoguide™ system for having the final instrument guidance being performed by the physician.
11. iSYS1 and Stealth Autoguide™ system for having real-time position information provided by an external platform and not by the device.
12. iSYS1 and Stealth Autoguide™ system for supporting manual and automatic robotic movements.
13. iSYS1 and Stealth Autoguide™ system for having tool guides as instrumentation.
14. iSYS1 and Stealth Autoguide™ for not requiring fiducial registration with pointer probe.
15. iSYS1 for not requiring optical registration for procedures performed with pre- and intra-operative imaging.
16. iSYS1 and Stealth Autoguide™ for not requiring ultrasound registration.
17. iSYS1 and Stealth Autoguide™ for having the user verifying the final accuracy.

Differences:

- The Stealth Autoguide™ system uses only optical navigation as a way to provide real-time position information whereas Micromate™ and the iSYS1 contain fiducial markers on the end-effector.
- The Stealth Autoguide™ system is used in combination with the StealthStation for planning and navigation. The iSYS1 and Micromate™ have an open software interface that can be used to align the systems to a surgical plan defined on a third-party planning station.
- The Stealth Autoguide™ system is used in combination with reusable surgical instruments specific to the defined indications, whereas the iSYS1 and Micromate™ rely on third-party sterile needle guides/tool guides and sterile drapes. Micromate™ uses different pre-approved sterile accessories than those used with iSYS1.
- While the Stealth Autoguide™ is indicated to be used by neurosurgeons only, the iSYS1 and Micromate™ are indicated to be used by any trained physician. This has no effects on safety and effectiveness.
- While the Stealth Autoguide™ uses proprietary reusable sterilizable instruments, the iSYS1 and Micromate™ use third-party sterile disposables.
- The Stealth Autoguide™ utilizes optical navigation and optical registration, whereas the iSYS1 and the Micromate™ do not. Instead, the iSYS1 and Micromate™ rely on the live fluoroscopy imaging and/or marker fiducials on the tool holder

Non-Clinical Performance Data

Testing was conducted on the Micromate™ 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:

- IEC 60601-1:2005+AMD1:2012 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for safety; Electromagnetic Compatibility – Requirements and Tests
- Software Verification and Validation testing verifying the operating system software requirements are met and software performs as intended
- Hardware Verification testing ensuring the hardware requirements identified for the system are met and hardware performs as intended (this includes, but is not limited to, reliability lifetime testing, functional testing, performance testing including accuracy)
- Usability Engineering was conducted in accordance with IEC 62366 demonstrating that the usability and human factors requirements were adequately met.

Statement of safety and effectiveness:

The Micromate™ is substantially equivalent to the legally marketed device iSYS1 (iSYS Medizintechnik GmbH). It is our opinion that the Micromate™ system does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.

Conclusion:

The Micromate™ system has been shown through comparison, pre-clinical and clinical performance data to be substantially equivalent to or better than the identified predicate device. The system has the same intended use and similar indications for use as the predicate device, while having similar technological characteristics and principles of operation.
The minor differences in indications or technological aspects do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled.