December 3, 2021

Therataxis, LLC
℅ Al Memmolo
President, Convergent Clinical, Inc.
6648 Surf Crest St.
Carlsbad, California 92011

Re: K201435
Trade/Device Name: Molecular Flow Simulations
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW, QRI
Dated: November 11, 2021
Received: November 15, 2021

Dear Al Memmolo:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K201435

Device Name
Molecular Flow Simulations

Indications for Use *(Describe)*

Molecular Flow Simulations is designed as a planning system for pre- and intra-operative planning of stereotactic or image-guided surgeries. It is specially designed to display anatomical images of a patient acquired with magnetic resonance (MR) or computed tomography (CT) scanners as well as images derived from diffusion tensor imaging (DTI)-data acquired with MR. Molecular Flow Simulations is a dedicated tool for planning trajectories of intracranial catheters. Guidelines for the catheter placement, such as from catheter suppliers, can be visualized and displayed to support the surgeon in improving catheter placement planning. The guidelines, in combination with anatomical information, can be used to suggest areas that are compliant with the guidelines. Molecular Flow Simulations does not generate or create rules for the placement of intracranial catheters by any means. Molecular Flow Simulations uses MR-DTI and T2- weighted MR images to suggest likely volumes of fluid distribution.

The primary mode of action for Molecular Flow Simulations is a device for creating stereotactic or image-guided surgical plans, especially for the creation of plans for the placement of intracranial catheters.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# Molecular Flow Simulations

## 510(k) Summary

**A. Device Information:**

| Category | Comments |
|---|---|
| Sponsor: | Therataxis, LLC<br>Johns Hopkins Eastern Building Suite B305<br>1101 East 33rd Street Baltimore, MD 21208<br>(443) 451-7154 |
| Correspondent Contact Information: | Al Memmolo<br>Convergent Clinical, Inc.<br>Carlsbad, CA 92011<br>Email: almemmolo@gmail.com |
| Device Common Name: | Planning System, Stereotaxic Instrument |
| Device Regulation & Name: | CFR 882.4560 Stereotaxic Instrument |
| Classification & Product Code:<br>510(k) Number: | Classification: Class II Product Code: HAW, QRI<br>K201435 |
| Device Proprietary Name: | Molecular Flow Simulations |

**Predicate Device Information:**

| | |
|---|---|
| Predicate Device: | iPlan Flow |
| Predicate Device Manufacturer: | Brainlab AG |
| Predicate Device Common Name: | iPlan Flow |
| Predicate Device Premarket Notification # | K053164 |
| Predicate Device Classification & Name | Classification: Class II<br>Name: Stereotaxic Instrument |
| Predicate Device Classification & Product Code: | Classification: Class II<br>Product Code: HAW |

**B. Date Summary Prepared**

December 3, 2021

**C. Description of Device**

Molecular Flow Simulations is a software tool running on a standard, standalone computer (PC or Laptop), or being accessible via the intranet connection, that can be used by surgeons for pre- or intraoperative planning of treatments based on stereotactic systems or image guided surgery systems. The system is a software-only medical device to be installed on common IT hardware.

## D. Indications for Use

Molecular Flow Simulations is designed as a planning system for pre- and intra-operative planning of stereotactic or image-guided surgeries. It is specially designed to display anatomical images of a patient acquired with magnetic resonance (MR) or computed tomography (CT) scanners as well as images derived from diffusion tensor imaging (DTI)-data acquired with MR. Molecular Flow Simulations is a dedicated tool for planning trajectories of intracranial catheters. Guidelines for the catheter placement, such as from catheter suppliers, can be visualized and displayed to support the surgeon in improving catheter placement planning. The guidelines, in combination with anatomical information, can be used to suggest areas that are compliant with the guidelines. Molecular Flow Simulations does not generate or create rules for the placement of intracranial catheters by any means. Molecular Flow Simulations uses MR-DTI and T2-weighted MR images to suggest likely volumes of fluid distribution.

The primary mode of action for Molecular Flow Simulations is a device for creating stereotactic or image-guided surgical plans, especially for the creation of plans for the placement of intracranial catheters.

## E. Comparison of the Technological Characteristics

| Characteristic | Application Device: Molecular Flow Simulations (K201435) | Predicate Device: iPlan Flow (K053164) | Impact on Substantial Equivalence |
|---|---|---|---|
| **Company** | Therataxis, LLC | Brainlab | - |
| **Regulation Number** | 882.4560 | 882.4560 | Identical |
| **Product Code** | HAW | HAW | Identical |
| **Intended Use** | Molecular Flow Simulations is designed as a planning system for pre- and intraoperative planning of stereotactic or image guided surgery treatments. It is specially designed to display anatomical images of a patient acquired with MR and/or CT as well as images derived from DTI-data acquired with Magnetic Resonance Imaging (MRI). | iPlan Flow is designed as a planning system for pre- and intraoperative planning of stereotactic or image guided surgery treatments. It is specially designed to display anatomical images of a patient acquired with MR and/or CT as well as images derived from DTI-data acquired with Magnetic Resonance Imaging (MRI). | Equivalent |

| | | | |
|---|---|---|---|
| **Indications for Use** | Molecular Flow Simulations is designed as a planning system for pre- and intra-operative planning of stereotactic or image-guided surgeries. It is specially designed to display anatomical images of a patient acquired with magnetic resonance (MR) or computed tomography (CT) scanners as well as images derived from diffusion tensor imaging (DTI)-data acquired with MR. Molecular Flow Simulations is a dedicated tool for planning trajectories of intracranial catheters. Guidelines for the catheter placement, such as from catheter suppliers, can be visualized and displayed to support the surgeon in improving catheter placement planning. The guidelines, in combination with anatomical information, can be used to suggest areas that are compliant with the guidelines. Molecular Flow Simulations does not generate or create rules for the placement of intracranial catheters by any means. Molecular Flow Simulations uses MR-DTI and T2- weighted MR images to suggest likely volumes of fluid distribution.<br><br>The primary mode of action for Molecular Flow Simulations is a device for creating stereotactic or image-guided surgical plans, especially for the creation of plans for the placement of intracranial catheters. | iPlan Flow is designed as a planning system for pre- and intraoperative planning of stereotactic or image guided surgery treatments. It is specially designed to display anatomical images of a patient acquired with MR and/or CT as well as images derived from DTI-data acquired with Magnetic Resonance Imaging (MRI). iPlan Flow is a dedicated tool for planning trajectories of intra-cranial catheters. Guidelines for the catheter placement e.g. from catheter suppliers can be visualized and displayed to support the surgeon in improving catheter placement planning. The guidelines, in combination with anatomical information, can be used to suggest areas that are compliant with the guidelines. iPlan Flow does not generate or create rules for the placement of intracranial catheters by any means. iPlan Flow uses MR-DTI and T2- weighted MR images to suggest likely volumes of fluid distribution.<br><br>The Primary mode of action for iPlan Flow is a device for creating treatment plans for stereotactic or image guided surgical treatment, especially for the creation of plans for the placement of intra-cranial catheters.<br><br>The treatment plans can be used in conjunction with other BrainLAB medical devices such as VectorVision for image guided surgical treatment. | Equivalent |

| | | | |
|---|---|---|---|
| **Technology** | Molecular Flow Simulations can be used for the planning of intracranial catheters, with image guided surgery. Guidelines for the exact placement of intracranial catheters can be visualized. These guidelines comprise the minimal depth of the catheter tip in the brain tissue, the minimal distance of the catheter tip from intra-cranial surfaces and the minimal distance between different catheter tips. The depth guideline can be calculated from the flow rate and the catheter diameter and warnings will be displayed if the trajectory of a planned catheter is likely to cross an intra-cranial surface. Molecular Flow Simulations is able to calculate a likely fluid distribution from the planned catheter positions to support the physician in his decision about appropriate catheter positions. These features enable the surgeon to better plan and place intra-cranial catheters. | iPlan Flow can be used for the planning of intracranial catheters, with image guided surgery. Guidelines for the exact placement of intracranial catheters can be visualized. These guidelines comprise the minimal depth of the catheter tip in the brain tissue, the minimal distance of the catheter tip from intra-cranial surfaces and the minimal distance between different catheter tips. The depth guideline can be calculated from the flow rate and the catheter diameter and warnings will be displayed if the trajectory of a planned catheter is likely to cross an intra-cranial surface. iPlan Flow is able to calculate a likely fluid distribution from the planned catheter positions to support the physician inhis decision about appropriate catheter positions. These features enable the surgeon to better plan and place intra-cranial catheters. | Technology is identical. |

| Characteristic | Application Device: Molecular Flow Simulations (K201435) | Predicate Device: iPlan Flow (K053164) | Impact on Substantial Equivalence |
|---|---|---|---|
| **Features** | Comprehensive Target Planning: Automatically defines margins around the tumor.<br><br>Guided Entry Point Planning: The sulcus detection feature automatically segments cerebrospinal fluid spaces as they are potential leakage pathways.<br><br>Guided Catheter Planning: Catheter planning guidelines indicate potential backflow and other drug leakage pathways around the catheter tip in order to maximize infusate distribution.<br><br>3D Distribution Simulation: The likely distribution of infusate for a given catheter position is predicted in 3D based on patient-specific information and mathematical modeling. Flux boundary conditions can be utilized. This more accurately models CED infusions, in which the infusate is delivered at a constant flow rate rather than a constant pressure.<br><br>3D capillary loss maps from DCE, poroelastic expansion of the extracellular space, and flux boundary modeling of the infusion sources. | Comprehensive Target Planning: Automatically defines margins around the tumor.<br><br>Guided Entry Point Planning: The sulcus detection feature automatically segments cerebrospinal fluid spaces as they are potential leakage pathways.<br><br>Guided Catheter Planning: Catheter planning guidelines indicate potential backflow and other drug leakage pathways around the catheter tip in order to maximize infusate distribution.<br><br>3D Distribution Simulation: The likely distribution of infusate for a given catheter position is predicted in 3D based on patient-specific information and mathematical modeling. | Equivalent |

## F. Summary of Supporting Data

Several tests were performed, in concordance with Duke University, using synthetic, animal and human imaging. Therefore, Molecular Flow Simulations does not raise any new questions regarding safety and effectiveness.

## G. Discussion of Performance Testing

All necessary testing has been performed with Molecular Flow Simulations to assure substantial equivalence to the predicate device.

Summary of non-clinical tests:

Molecular Flow Simulations is a software application; therefore no electrical safety or electromagnetic testing was required.

Testing conducted to demonstrate software validation and substantial equivalence included:

- Verification testing that product meets product performance and functional specifications.
- Verification that data submitted is stored properly to maintain data integrity (e.g. no loss of data or corruption).
- User performance testing to demonstrate adequate instructional utility of the User Manual.

The Requirements Traceability Matrix (RTM) provides a mapping between requirements, risks, test cases, and shows related test results. The RTM confirms that there was a test case authored and executed for all requirements and any applicable risks.

After extensive bench testing to performance requirements and criteria established in accordance with application of ISO 14971, risk analysis standard, no new issues of safety, performance, technology or intended use were identified.

## H. Conclusion

Upon reviewing the technical information provided in this submission and comparing intended use, principle of operation, performance data, and overall technological characteristics, Molecular Flow Simulations is determined to be substantially equivalent to the predicate device.