December 29, 2022

Anuncia Medical, Inc.
Natalie Eagleburger
VP of Regulatory, Clinical and Quality
1355 N Scottsdale Rd, Suite 370
Scottsdale, Arizona 85257

Re: K223603
Trade/Device Name: ReFlow System Mini and ReFlow Mini Flusher
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 2, 2022
Received: December 2, 2022

Dear Natalie Eagleburger:

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 -S

Digitally signed by Adam D. Pierce -S
Date: 2022.12.29 15:47:35 -05'00'

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)*
K223603

Device Name
ReFlow® System Mini
ReFlow® Mini Flusher

Indications for Use *(Describe)*
The ReFlow® System Mini and the ReFlow® Mini Flusher, used as components of a shunt system, are for use in the treatment of patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated. The miniaturized ReFlow Mini Flusher may be used by a qualified clinician as a tool to facilitate a noninvasive retrograde fluid flush of the shunt ventricular catheter to unblock inlet holes to restore, increase, or maintain CSF flow. When used with the ReFlow Ventricular Catheter, the flush can also open the ReFlow Ventricular Catheter's relief membrane to restore, increase, or maintain CSF flow. The ReFlow System Mini components are not intended to change the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow Mini Flusher may be used as directed for noninvasive flushing by a trained healthcare professional in-clinic or by a trained caregiver or adult patient in a non-clinical environment.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

ReFlow® System Mini

I. SUBMITTER

Anuncia Medical, Inc.
1355 North Scottsdale Rd, Suite 370
Scottsdale, AZ 85257, USA

Phone: 978-942-5600
Contact Person: Natalie Eagleburger
Date Prepared: December 29, 2022

II. DEVICE

Trade Name:	ReFlow® System Mini, ReFlow® Mini Flusher
510(k) Number:	K223603
Common or Usual Name:	CSF Shunt System
Classification Name:	Shunt, Central Nervous System and Components
Regulatory Class:	Class II
Product Code and Regulation:	JXG, 21CFR 882.5550

III. PREDICATE DEVICE

Primary Predicate

ReFlow® System Mini (K221918)

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The ReFlow® System Mini (RSM) consists of the ReFlow® Mini Flusher and ReFlow® Ventricular Catheter, both implantable components of a cerebrospinal fluid (CSF) shunt system used in the treatment of patients with hydrocephalus and other CSF disorders when draining or shunting of CSF is medically indicated. The ReFlow Mini Flusher is also sold separately. A ventricular catheter is surgically implanted in the ventricle of the brain and connected distally to the ReFlow Mini Flusher. The ventricular catheter may be the ReFlow Ventricular Catheter or a commercially available ventricular catheter (only the ReFlow Ventricular Catheter is provided as part of the ReFlow System Mini). The ReFlow Mini Flusher is then connected to a commercially available flow/pressure regulating valve (not provided as part of the ReFlow System Mini).

The flusher contains a fluid reservoir and, when implanted as part of a shunt system, may be used at the treating physician's discretion as a tool to non-invasively facilitate a one-way retrograde pulse of fluid through the ventricular catheter to potentially restore, increase, or maintain CSF flow in the shunt system by potentially unblocking the proximal catheter. The flusher is noninvasively actuated by depressing the flusher dome, which is palpable underneath the patient's scalp, to send a controlled and limited pulse of a consistent volume of fluid (patient's CSF or sterile saline introduced from the priming procedure before implant) within the closed system. The fluid flush generated by the flusher is intended to potentially unblock shunt ventricular catheter inlet holes. In cases when the ReFlow Mini Flusher is used with the ReFlow Ventricular Catheter, the flush will open the ReFlow Ventricular Catheter emergency relief membrane to provide a secondary fluid pathway to restore or increase CSF flow in the shunt system if inlet holes are not able to be unblocked by the flush actuation. Once this relief membrane is open, subsequent flushes with the flusher may not be sufficient to unblock the secondary fluid pathway, which may become occluded in a manner similar to that of the proximal catheter inlet holes.

After flushing the ReFlow Mini Flusher, palpation to confirm the dome has returned to its original shape may be used to determine that the reservoir has refilled prior to flushing a second time. Refilling of the flusher reservoir can be confirmed by palpation of the dome, indicating that CSF from the ventricles is able to flow through the ventricular catheter to the ReFlow Mini Flusher. The clinician must use his/her medical judgment and standard practice at his/her institution to care for the patient pre, during, and post utilization of the ReFlow System Mini.

The ReFlow System Mini and the ReFlow Mini Flusher do not regulate the flow/pressure of the shunt system. A flow regulating shunt valve is not provided with the ReFlow System Mini or ReFlow Mini Flusher. During passive flow, fluid from the ventricular catheter flows freely through the ReFlow Mini Flusher to the flow regulating valve. The ReFlow System Mini and the ReFlow Mini Flusher are designed to be compatible with most commercially available flow/pressure regulative valves with standard inlet connectors. Additionally, the Reflow Mini Flusher component utilizes a common barbed connector designed to be compatible with most commercially available ventricular catheters in addition to the ReFlow Ventricular Catheter.

The ReFlow System Mini components are provided in two packaging configurations as follows:

ReFlow® System Mini

- Package Contents: ReFlow Ventricular Catheter and ReFlow Mini Flusher System
  - Ventricular Catheter (Qty: 1)
  - Flusher (Qty: 1)
  - Stylet (Qty: 1)

ReFlow® Mini Flusher

- Package Contents: ReFlow Mini Flusher only
  - Flusher (Qty: 1)

ReFlow® Ventricular Catheter Description

The **ReFlow® Ventricular Catheter** is made from silicone elastomer and barium sulfate, with an inner diameter of 1.27 mm and an outer diameter of 2.54 mm. The Ventricular Catheter is 150 mm in length and is supplied with 20 inlet holes (4 rows of 5 holes at the proximal end). There is a thin silicone relief membrane at the proximal end of the catheter distal to the inlet holes. The relief membrane is designed to open via manual depression of the Mini Flusher dome to provide a noninvasive and consistent method to restore or increase flow in a suspected non-flowing or slow-flowing shunt system. The relief membrane has only been tested as a one-time use feature. This Ventricular Catheter is MR safe and not made with natural rubber latex.

A stainless-steel stylet is provided with the ReFlow Ventricular Catheter for insertion of the catheter into the ventricle. This stylet is MR Unsafe and not made with natural rubber latex.

ReFlow® Mini Flusher Description

The **ReFlow® Mini Flusher** contains a fluid reservoir encased in a flexible silicone housing. The device utilizes a common barbed connector that allows direct connection to the ventricular catheter. The device has a flush dome (reservoir). The ReFlow System Mini offers a noninvasive means to facilitate a retrograde flush of the ventricular catheter to either unblock inlet holes or open its relief membrane to restore, increase, or maintain CSF flow. Retrograde flushing of the ventricular catheter is performed by depression of the flusher dome. When actuated as per the treating physician's guidance and instruction, the flusher sends a controlled and limited retrograde pulse of fluid (CSF or sterile saline from the priming procedure before implant) towards the ventricular catheter to either maintain or resume flow by opening the suspected blocked inlet holes or open the relief membrane of the ReFlow Ventricular Catheter to restore flow in the shunt system.

The ReFlow Mini Flusher does not regulate the flow of the shunt system or inhibit the function of the flow regulating valve. During passive flow, fluid from the ventricular catheter flows freely through the Mini Flusher. A flow regulating shunt valve is not provided with the ReFlow System Mini. The ReFlow Mini Flusher is compatible with shunt valves with standard barbed connections.

The Mini Flusher is MR safe and is not made with natural rubber latex.

V. INDICATIONS FOR USE

The ReFlow® System Mini and the ReFlow® Mini Flusher, used as components of a shunt system, are for use in the treatment of patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated. The miniaturized ReFlow Mini Flusher may be used by a qualified clinician as a tool to facilitate a noninvasive retrograde fluid flush of the shunt ventricular catheter to unblock inlet holes to restore, increase, or maintain CSF flow. When used with the ReFlow Ventricular Catheter, the flush can also open the ReFlow Ventricular Catheter's relief membrane to restore, increase, or maintain CSF flow. The ReFlow System Mini components are not intended to change the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow Mini Flusher may be used as directed for noninvasive flushing by a trained healthcare professional in-clinic or by a trained caregiver or adult patient in a non-clinical environment.

The Indications for Use statement cleared in the predicate submission K221918 did not contain language distinguishing the use of the ReFlow Mini Flusher component with other ventricular catheters from its use specifically with the ReFlow Ventricular Catheter. The intent of this premarket submission is to clarify the indication statement to distinguish this use and align it with the intended use in the predicate labeling. This clarification does not raise different questions of safety and effectiveness.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device incorporates the same technological characteristics as that of the predicate device and the design is identical to the currently cleared version. A change has been made to package the ReFlow Mini Flusher component by itself (without the ReFlow Ventricular Catheter) in addition to the predicate configuration that contains both implantable components (and a non-implantable stylet used to facilitate catheter placement). Both subject and predicate devices are implantable components of a cerebrospinal fluid (CSF) shunt system used in the treatment of patients with hydrocephalus and other CSF disorders when draining or shunting of CSF is medically indicated.

	SUBJECT DEVICE **Anuncia ReFlow® System Mini and ReFlow® Mini Flusher (K223603)**	**PRIMARY PREDICATE** **Anuncia ReFlow® System Mini (K221918)**	**Equivalence Comparison**
Regulation	21CFR882.5550	21CFR882.5550	Same
Class	Class II	Class II	Same
Product Code	JXG	JXG	Same
Trade Name	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Same
Indications for Use	The ReFlow® System Mini and the ReFlow® Mini Flusher, used as components of a shunt system, are for use in the treatment of patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated. The miniaturized ReFlow Mini Flusher may be used by a qualified clinician as a tool to facilitate a noninvasive retrograde fluid flush of the shunt ventricular catheter to unblock inlet holes to restore, increase, or maintain CSF flow. When used with the ReFlow Ventricular Catheter, the flush can also open the ReFlow Ventricular Catheter's relief membrane to restore, increase, or maintain CSF flow. The ReFlow System Mini components are not intended to change the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow Mini Flusher may be used as directed for noninvasive flushing by a trained healthcare professional in-clinic or by a trained caregiver or adult patient in a non-clinical environment.	The ReFlow™ System Mini, components of a shunt system, is for use in the treatment of patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated. The miniaturized ReFlow Flusher may be used by a qualified clinician as a tool to facilitate a noninvasive retrograde fluid flush of the ReFlow Ventricular Catheter to unblock inlet holes or open its relief membrane to restore, increase, or maintain CSF flow. The ReFlow System Mini is not intended to change standard care practices for diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. As part of standard of care clinical practice, and under the care, direction, and instruction of the treating physician, the ReFlow System Mini be used as directed for noninvasive flushing by a trained healthcare professional in-clinic or by a trained caregiver or adult patient in a non-clinical environment.	Intended Use: Same Indications: Equivalent
Target Population	Patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated	Patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated	Same
Anatomical Sites	Brain ventricle and head	Brain ventricle and head	Same

	SUBJECT DEVICE Anuncia ReFlow® System Mini and ReFlow® Mini Flusher (K223603)	PRIMARY PREDICATE Anuncia ReFlow® System Mini (K221918)	Equivalence Comparison
Compatibility with environment and other devices	Compatible with current shunt systems and accessories	Compatible with current shunt systems and accessories	Same
Sterility	Terminally sterilized for 10^{-6} SAL with no damage to system components. Validated per ANSI/AAMI/ISO 11137-2; Sterilization of health care products - Radiation	Terminally sterilized for 10^{-6} SAL with no damage to system components. Validated per ANSI/AAMI/ISO 11137-2; Sterilization of health care products - Radiation	Same
Packaging	Packaging maintains sterility and protects device. Tray, pouch, box. Packaging configuration includes catheter and flusher packaged together as well as flusher component packaged separately.	Packaging maintains sterility and protects device. Tray, pouch, box. Catheter and flusher packaged together.	Equivalent

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Testing was conducted on the ReFlow System Mini to demonstrate that it meets defined design requirements and can perform in a manner equivalent to devices currently on the market used for its intended use. Testing included verification and validation bench testing and human factors evaluations in a simulated clinical use model per the available guidance. The design, testing, and technical information provided for the RSM also comply with the applicable sections of ISO 7197:2006 (E), Neurosurgical Implants - Sterile, single-use hydrocephalus shunts and components [Including: Technical Corrigendum 1 (2007)] and ASTM F647: 94 (2014), Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application. The table below summarizes the performance testing conducted.

Test	Test Method Summary	Results and Conclusions
Design Verification Bench Testing: Pressure 1m Water Column Leak Test, Occlusion Studies, and Pressure Flow Characterization	Conducted testing and reported results in accordance ISO 7197:2006 (E), Neurosurgical Implants - Sterile, single-use hydrocephalus shunts and components and ASTM F647: 94(2014), Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	All results met acceptance criteria and demonstrate the RSM is suitable for its intended use and is substantially equivalent to the predicate device.

Manufacturing and traceability of devices tested were conducted in accordance with 21 CFR Part 820 Good Manufacturing Practices. In all instances, the RSM functioned as intended and the results observed were as expected. These test results confirm that RSM complies with the recognized standards, meets the design specifications and performance requirements for the intended use, and is substantially equivalent to the predicate.

VIII. CONCLUSIONS

The ReFlow System Mini is substantially equivalent to the primary predicate device (K221918). The ReFlow System Mini and its predicate share the same Product Code and classification as components of a CSF Shunt System. The ReFlow System Mini has the same intended use as the primary predicate device and equivalent indications for use. The ReFlow System Mini also has an identical design and technological characteristics as the primary predicate device. Minor clarifications in the indications for use do not raise different questions of safety and efficacy when all listed warnings and cautions are followed.

The results from preclinical evaluations demonstrate that the technological and performance characteristics of the ReFlow System Mini meet defined design requirements. Performance data demonstrate that the ReFlow System Mini performs as intended and is substantially equivalent to its predicate. This conclusion is based upon the device equivalence in the device's (1) design, (2) material technological characteristics, (3) material suppliers, (4) principles of operation, (5) and intended use.