September 29, 2022

Anuncia Medical, Inc.
Natalie Eagleburger
Senior Director, Regulatory, Clinical, Quality
1355 N Scottsdale Rd, Suite 370
Scottsdale, Arizona 85257

Re: K221918
Trade/Device Name: ReFlow System Mini
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: June 30, 2022
Received: July 1, 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, 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)*
K221918

Device Name
ReFlow System Mini

Indications for Use *(Describe)*
The ReFlow System Mini, used as 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 the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow System Mini 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.

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: September 28, 2022

II. DEVICE

Trade Name:	ReFlow System Mini
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 Ventricular Catheter and Flusher System (K172006)
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 catheter is surgically implanted in the ventricle of the brain and connected distally to the Mini Flusher. The 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 or maintain flow in the shunt system by 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. In cases where inlet holes are not able to be unblocked by a flush actuation, 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.

After flushing the device, 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 does not regulate the flow/pressure of the shunt system. A flow regulating shunt valve is not provided with the ReFlow System Mini. During passive flow, fluid from the ventricular catheter flows freely through the Mini Flusher to the flow regulating valve. The ReFlow System Mini is 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.

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.

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, used as 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 the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow System Mini 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	SUBJECT DEVICE **Anuncia** **ReFlow System Mini** **(K221918)**	**PRIMARY PREDICATE** **Anuncia** **ReFlow Ventricular System** **(K172006)**	**Equivalence Comparison**
Regulation	21CFR882.5550	21CFR882.5550	Same
Class	Class II	Class II	Same

	SUBJECT DEVICE **Anuncia** **ReFlow System Mini** **(K221918)**	**PRIMARY PREDICATE** **Anuncia** **ReFlow Ventricular System** **(K172006)**	**Equivalence Comparison**
Product Code	JXG	JXG	Same
Trade Name	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Same
Intended Use	The ReFlow System Mini, used as 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 the diagnosis, treatment, or follow-up of patients with proximal catheter occlusions. Under the care, direction, and instruction of the treating physician, the ReFlow System Mini 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 Ventricular Catheter and Flusher System (ReFlow System) is for use in the treatment of patients with hydrocephalus, as components of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated. The ReFlow Flusher may be used by a qualified clinician as a tool to facilitate a non-invasive retrograde fluid flush of the ReFlow Ventricular Catheter to unblock inlet holes or open its relief membrane to restore or increase CSF flow in a non-flowing shunt. The ReFlow flusher is not intended to change standard of care practices for diagnosis, treatment, or follow-up of patients with proximal catheter occlusions.	Intended Use: Equivalent Indications: Equivalent
Indications for Use	Treatment of hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated, as components of a shunt system.	Treatment of hydrocephalus, as components of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated	Equivalent
	Drains CSF to reduce intracranial pressure and CSF volume and restore, increase, or maintain flow in a shunt.	Drains CSF to reduce intracranial pressure and CSF volume and restore or increase in suspected non-flowing shunt	Equivalent.
	Proximal pumping of the reservoir to restore, increase, or maintain CSF flow in a shunt.	Proximal pumping of the reservoir to temporarily restore or increase CSF flow in suspected non-flowing shunts.	Equivalent
	Implantable	Implantable	Same
	Single use	Single use	Same

	SUBJECT DEVICE Anuncia ReFlow System Mini (K221918)	PRIMARY PREDICATE Anuncia ReFlow Ventricular System (K172006)	Equivalence Comparison
Target Population	Patients with hydrocephalus or conditions where draining or shunting of cerebrospinal fluid (CSF) is medically indicated	Patients with hydrocephalus	Equivalent
Anatomical Sites	Brain ventricle and head	Brain ventricle and head	Same
Where Used	Operating Room (implant) Clinical and Non-Clinical Environments per treating physician discretion (actuation or flushing)	Operating Room (implant) Clinical and Non-Clinical Environments per treating physician discretion (actuation or flushing)	Same
Energy Used	None	None	Same
Human Factors	Labeling indicates size and length	Labeling indicates size and length	Same
	Labeling indicates flow vs. pressure labels	Labeling indicates flow vs. pressure labels	Same
	Can be activated (flushed) by healthcare provider, caregiver, or adult patient under the direction, training, and guidance of the treating physician.	Can be activated (flushed) by a qualified clinician	Equivalent. Flushing by a trained health care provider (other than the treating physician), a caregiver, or adult patient under the care of and as directed by the treating physician was demonstrated by human factors and usability performance testing to not require special skills or education.
	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Same
Design	Designed to be placed in the ventricle of the brain and under the scalp	Designed to be placed in the ventricle of the brain and under the scalp	Same
	Flexible catheter to remain implanted in the brain	Flexible catheter to remain implanted in the brain	Same
	Series of holes at distal end of the catheter for fluid movement	Series of holes at distal end of the catheter for fluid movement	Same
	20 flow holes	20 flow holes	Same
	4 lines of 5 holes	4 lines of 5 holes	Same
	Bullet shaped tip	Bullet shaped tip	Same

	SUBJECT DEVICE Anuncia ReFlow System Mini (K221918)	PRIMARY PREDICATE Anuncia ReFlow Ventricular System (K172006)	Equivalence Comparison
	A single relief membrane distal to the proximal holes of the catheter to open at a threshold pressure for temporarily restoration of fluid movement	A single relief membrane distal to the proximal holes of the catheter to open at a threshold pressure for temporarily restoration of fluid movement	Same
	Length from proximal tip to the most distal holes and relief membrane is 0.720"	Length from proximal tip to the most distal holes and relief membrane is 0.720"	Same
	Catheter is not impregnated with antimicrobial agents.	Catheter is not impregnated with antimicrobial agents.	Same
	Barium sulfate-filled catheter	Barium sulfate-filled catheter	Same
	Inner diameter of catheter: 0.050"	Inner diameter of catheter: 0.050"	Same
	Outer diameter of catheter: 0.100"	Outer diameter of catheter: 0.100"	Same
	Catheter length: 15cm initially (other common lengths may be offered)	Catheter length: 15cm initially (other common lengths may be offered)	Same
	Length markings: 1 dot at 10cm and 2 dots at 15cm	Length markings: 1 dot at 10cm and 2 dots at 15cm	Same
	Stylet for catheter insertion	Stylet for catheter insertion	Same
	Reservoir (Rickham or comparable). Not tested or made as a claim.	Reservoir (Rickham or comparable). Not tested or made as a claim.	Same
	Right angle clip compatible (not provided)	Right angle clip compatible (not provided)	Same
	Flushing - unidirectional control by occluders	Flushing - unidirectional control by occluders	Same
	Flush direction only towards ventricle (proximal)	Flush direction only towards ventricle (proximal)	Same
	Restore, increase, or maintain flow through a catheter	Increases flow through a non-flowing catheter	Equivalent
	Flow regulation (allows passive flow for use in-line with a one-way check valve to regulate flow in system)	Flow regulation (allows passive flow for use in-line with a one-way check valve to regulate flow in system)	Same
	Fluid filled reservoir less than 0.5mL	Fluid filled reservoir less than 0.5 mL	Same
	Barb fittings for connection to ventricular catheter and shunt valve	Barb fittings for connection to ventricular catheter and shunt valve	Same
	Series of channels to allow fluid movement from dome into ventricular catheter and fluid from the ventricular catheter to dome and rest of shunt system	Series of channels to allow fluid movement from dome into ventricular catheter and fluid from the ventricular catheter to dome and rest of shunt system	Same

	SUBJECT DEVICE **Anuncia** **ReFlow System Mini** **(K221918)**	**PRIMARY PREDICATE** **Anuncia** **ReFlow Ventricular System** **(K172006)**	**Equivalence Comparison**
	Inner channel diameter: greater than 1mm	Inner channel diameter: greater than 1mm	Same Passive flow channel diameter meets ISO 7197:2006
	19mm in length, 23mm in width, 9mm in height	40mm in length 17mm in width 10mm height	Equivalent to predicate and size/dimension acceptable to user per human factors studies conducted
	Reservoir and shunt accessories withstand use forces	Reservoir and shunt accessories withstand use forces	Same
	Can be used with dimensionally compatible shunt system components	Can be used with dimensionally compatible shunt system components	Same
	Low profile for implantation under the scalp	Low profile for implantation under the scalp	Same
	Soft and flexible outer housing	Soft and flexible outer housing	Same
	n/a	Rigid sections in the housing to seat valves	n/a
	Occluders (distal drainage channel is occluded during flush)	Occluders (distal drainage channel is occluded during flush)	Same
	Complies with ASTM F647094 Section 6.4.1 with respect to Printing to indicate direction of flow and position	Complies with ASTM F647094 Section 6.4.1 with respect to Printing to indicate direction of flow and position	Equivalent
Performance	Retrograde pulse into the ventricular catheter (created by manual pumping - depressing dome/flusher with a fixed reservoir volume)	Retrograde pulse into the ventricular catheter (created by manual pumping - depressing dome/flusher with a fixed reservoir volume)	Same
	One way flow between the reservoir and ventricular catheter when device is pumped	One way flow between the reservoir and ventricular catheter when device is pumped	Same
	Reservoir refills after pumping	Reservoir refills after pumping	Same
	Normal shunt function resumes after pumping	Normal shunt function resumes after pumping	Same
	Catheter diverts fluid from ventricle	Catheter diverts fluid from ventricle	Same
	Relief membrane remains open after activating	Relief membrane remains open after activating	Same

	SUBJECT DEVICE Anuncia ReFlow System Mini (K221918)	PRIMARY PREDICATE Anuncia ReFlow Ventricular System (K172006)	Equivalence Comparison
Materials	Ventricular Catheter: silicone with BaSO4 filler, relief membrane silicone	Ventricular Catheter: silicone with BaSO4 filler, relief membrane silicone	Same
	Valves: silicone	Valves: silicone	Same
	Dome/outer housing: silicone	Dome/outer housing: silicone	Same
Biocompatibility	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Same
	Non-pyrogenic	Non-pyrogenic	Same
Compatibility with environment and other devices	Safe in an x-ray environment	Safe in an x-ray environment	Same
	Compatible with current shunt systems and accessories	Compatible with current shunt systems and accessories	Same
	Compatible with long term CSF contact and saline	Compatible with long term CSF contact and saline	Same
Radiopacity	BaSO4 filled silicone elastomer	BaSO4 filled silicone elastomer	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
Mechanical Safety	Manual flushing (pumping) generates equivalent ventricular suction/flushing with no valve damage or alteration	Manual flushing (pumping) generates equivalent ventricular suction/flushing with no valve damage or alteration	Same
Chemical Safety	Saline, CSF	Saline, CSF	Same
MR Labeling	MR Safe	MR Safe	Same
Radiation Safety	X-ray Safe	X-ray Safe	Same
Packaging	Packaging maintains sterility and protects device. Tray, pouch, box. Catheter and flusher packaged together.	Packaging maintains sterility and protects device. Tray, pouch, box. Catheter and flusher packaged together.	Equivalent

	SUBJECT DEVICE Anuncia ReFlow System Mini (K221918)	PRIMARY PREDICATE Anuncia ReFlow Ventricular System (K172006)	Equivalence Comparison
Shelf Life	Labeled shelf life (expiration) will be based on real time and accelerated aging shelf-life studies from 6 months up to 5 years.	Labeled shelf life (expiration) will be based on real time and accelerated aging shelf-life studies up to 3 years.	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
Particulate	Units will undergo particulate testing to evaluate that the number of particulates generated from both exterior and interior lumen of the ReFlow Mini Flusher, under simulated use conditions, does not pose any safety risks.	All results met acceptance criteria and demonstrate that the RSM performance is suitable for its intended use and is substantially equivalent to the predicate device.
Design Verification Bench Testing	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.
Reliability and System Level Functional Test	Testing was conducted to verify the reliability of the ReFlow System Mini to function during its expected useful life and meet requirements of 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.
Usability and human factors testing	Human Factors and Usability evaluations for critical tasks according to ReFlow Mini labeling were conducted in accordance with ANSI/AAMI HE 75, Human Factors Engineering Design of Medical Devices, IEC 62366:2007, Medical Devices - Application of Usability Engineering to Medical Devices, and FDA Guidance (Jun 22, 2011) Human Factors Draft Guidance.	RSM is deemed to meet its specifications for its intended use and is substantially equivalent to the predicate device. In all cases, the acceptance criteria were met, and the device performed as expected according to its specifications and in compliance with applicable recognized standards.

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 the ReFlow Ventricular System (K172006). The ReFlow System Mini and its predicate device 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 Ventricular System also has a very similar design and similar technological characteristics as the primary predicate device. Minor differences in design 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.