January 23, 2018

Alcyone Lifesciences, Inc.
% Elsa Chi Abruzzo, RAC, FRAPS
President & CEO
Cygnus Regulatory
3753 Vineyard Place
Cincinnati, Ohio 45226

Re: K172006
Trade/Device Name: Alivio Ventricular Catheter and Flusher System (Alivio System)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 9, 2017
Received: October 10, 2017

Dear Elsa Chi Abruzzo:

This letter corrects our substantially equivalent letter of November 9, 2017.

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172006

Device Name
Alivio Ventricular Catheter and Flusher System (Alivio System)

Indications for Use *(Describe)*
The Alivio Ventricular Catheter and Flusher System (Alivio 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 Alivio Flusher may be used by a qualified clinician as a tool to facilitate a non-invasive retrograde fluid flush of the Alivio Ventricular Catheter to unblock inlet holes or open its relief membrane to restore or increase CSF flow in a non-flowing shunt. The Alivio Flusher is not intended to change standard care practices for diagnosis, treatment, or follow-up of patients with proximal catheter occlusions.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY - K172006

Alivio Ventricular Catheter and Flusher System (Alivio System)

Company Name: Alcyone Lifesciences, Inc.

Company Address: 250 Jackson Street
Mill No. 5, Unit 494
Lowell, Massachusetts 01852, USA

Phone: 978-709-1946

Facsimile: 978-451-7646

Contact Person: Elsa Chi Abruzzo, RAC, FRAPS

Date Prepared: June 30, 2017

Trade Name: Alivio Ventricular Catheter and Flusher System (Alivio System)

Common or Usual Name: CSF Shunt System

Classification Name: Shunt, Central Nervous System and Components

Classification: Class II

Product Code and Regulation: JXG, 21CFR 882.5550

Classification Panel: Neurology

Predicate Device:

Primary Predicate
Integra™ Contour-Flex™ Valve and Shunt System (K033698)

Reference Predicates
NeuroDX Development ShuntCheck© III (K123554)

Codman® Medos® Ventricular Catheter (K944222)

Intended Use / Indications for Use

The Alivio Ventricular Catheter and Flusher System (Alivio 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 Alivio Flusher may be used by a qualified clinician as a tool to facilitate a non-invasive retrograde fluid flush of the Alivio Ventricular Catheter to unblock inlet holes or open its relief membrane to restore or increase CSF flow in a non-flowing shunt. The Alivio Flusher is not intended to change standard care practices for diagnosis, treatment, or follow-up of patients with proximal catheter occlusions.

Description of Device

The Alivio System, consisting of the Alivio Flusher and Alivio Ventricular Catheter, is an implantable component of a CSF Shunt System used in the treatment of patients with Hydrocephalus. The Ventricular Catheter is implanted in the ventricle and connected distally to the Flusher, which is in turn connected to a commercially available flow regulating valve (not provided as part of the Alivio System).

Similar to manual pumping of a flow regulating valve or performing an invasive shunt tap via the flow regulating valve; the Alivio Flusher, a fluid reservoir, may be used by a qualified clinician as a tool to facilitate a non-invasive retrograde fluid flush to the Alivio Ventricular Catheter to unblock occluded, proximal inlet holes. If the inlet holes are not able to be unblocked, the retrograde fluid flush will open the relief membrane of the Alivio Ventricular Catheter, creating a new fluid pathway to restore or increase CSF flow in a non-flowing shunt with occluded inlet holes. Once the relief membrane has been used to restore flow in a non-flowing shunt, subsequent retrograde fluid flushing of the Alivio Ventricular Catheter with the Alivio Flusher may not be sufficient to reopen the relief membrane, which may become occluded similar to proximal catheter inlet holes.

After flushing the device, standard methods of care should be used to determine that the reservoir is refilled prior to flushing a second time. Similar to commercially available reservoirs used in shunt systems, refilling of the Flusher reservoir can be confirmed by palpation of the dome. Repeated flushing of the device with an empty reservoir may not be effective. 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 Alivio System.

The Alivio Flusher does not regulate flow of the shunt system. A flow regulating shunt valve is not provided with the Alivio System. During passive flow, fluid from the ventricular catheter flows freely, without restriction through the passive flow channel of the Flusher. The Alivio System is compatible and has been tested with the Integra® Contour-Flex™ Valve. The Alivio System is designed to be compatible with all commercially available flow regulating valves with standard inlet connectors, similar to the inlet connector of the Integra® Contour-Flex™ Valve.

Ventricular Catheter Description

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

A stainless-steel stylet is provided with the Alivio Ventricular Catheter for insertion of the catheter into the ventricle.

Flusher Description

The **Alivio Flusher** is a reservoir system encased in a flexible silicone housing. The device consists of a common barbed connector that allows direct connection to the ventricular catheter. The device has a flush dome (reservoir) that feeds into a rigid encased flush valve. The flush valve opens at a predetermined pressure and sends a controlled retrograde pulse of fluid towards the ventricular catheter to either open the blocked inlet holes or open the relief membrane.

The Alivio Flusher does not regulate flow of the shunt system or inhibit the function of the flow regulating valve. A flow regulating shunt valve is not provided with the Alivio System. The Alivio Flusher is compatible with all shunt valves with standard barbed connections. During passive flow, fluid from the ventricular catheter flows freely, without restriction through the passive flow channel of the Flusher.

The Alivio Flusher offers the clinician a non-invasive means to flush the ventricular catheter in the case of obstructed flow through the ventricular catheter. At the clinician's discretion, retrograde flushing of the ventricular catheter can be performed by depression of the flush dome, which sends a controlled and limited pulse of fluid (CSF, or sterile saline introduced from the priming procedure before implant) into the ventricular

catheter to resume flow by opening suspected blocked inlet holes or opening the relief membrane of the Alivio Ventricular Catheter to restore antegrade flow in the shunt system.

During flushing, the passive channel is manually occluded to create temporary one-way flow into the ventricular catheter. After the controlled and limited pulse of fluid is sent from the flusher and the dome is released, the flush dome refills with CSF from the ventricular catheter and resumes free flowing fluid through the passive flow channel.

Once the relief membrane has been used to restore flow in a non-flowing shunt system, subsequent retrograde fluid flushing of the Alivio Ventricular Catheter with the Alivio Flusher may not be sufficient to reopen the relief membrane, which may become occluded similar to proximal catheter inlet holes. 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 Alivio System.

The Alivio System does not provide a mechanism for detecting obstruction or restricted flow.

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

Technological Characteristics

	SUBJECT DEVICE Alcyone Alivio System (K172006)	**PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)**	**REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)**	**REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)**	**Equivalence Comparison**
Regulation	21CFR882.5550	21CFR882.5550	21CFR882.5550	21CFR882.5550	Equivalent
Class	Class II	Class II	Class II	Class II	Equivalent
Product Code	JXG	JXG	JXG	JXG	Equivalent
Trade Name	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Shunt, Central Nervous System and Components	Equivalent
Intended Use	The Alivio Ventricular Catheter and Flusher System (Alivio 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 Alivio Flusher may be used by a qualified clinician as a tool to facilitate a non-invasive retrograde fluid flush of the Alivio Ventricular Catheter to unblock inlet holes or open its relief membrane to restore or increase CSF flow in a non-flowing shunt. The Alivio Flusher is not intended to change standard care practices for diagnosis, treatment, or follow-up of patients with proximal catheter	For Use in the treatment of patients with hydrocephalus. The valve is a component of a system designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or peritoneal cavity.	Aids in the detection of flow in implanted CSF shunts. ShuntCheck includes Micro-Pumper, a component which may be used to temporarily increase CSF flow in suspected non-flowing, patent shunts during the ShuntCheck test. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.	For use in the treatment of hydrocephalus as a component of shunt system when draining or shunting of CSF is indicated.	Equivalent

	SUBJECT DEVICE Alcyone Alivio System (K172006)	PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)	REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)	REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)	Equivalence Comparison
	occlusions.				
Indications for Use	Treatment of hydrocephalus	Treatment of hydrocephalus	Treatment of hydrocephalus	Treatment of hydrocephalus	Equivalent
	Drains CSF to reduce intracranial pressure and CSF volume and increases flow in a suspected non-flowing shunt	Drains CSF to reduce intracranial pressure and CSF volume	Temporarily increases flow in a suspected non-flowing, patent shunt	Drains CSF to reduce intracranial pressure and CSF volume	Equivalent
	Proximal pumping of the reservoir to increase CSF flow in suspected non-flowing shunts.	Proximal and distal pumping and injection of the reservoir to regulate flow	Vibrational pumping of the reservoir to temporarily increase CSF flow in suspected non-flowing, patent shunts.	N/A	Equivalent
	Implantable	Implantable	Not Implantable	Implantable	Equivalent
	Single use	Single use	Single use	Single use	Equivalent
Target Population	Patients with hydrocephalus	Patients with hydrocephalus	Patients with hydrocephalus	Patients with hydrocephalus	Equivalent
Anatomical Sites	Brain ventricle and Head	Head	Head	Brain Ventricle	Equivalent
Where Used	Operating Room	Operating room	Operating room	Operating room	Equivalent
Energy Used	None	None	None	None	Equivalent
Human Factors	Labeling indicates size and length	Labeling indicates size and length	Labeling indicates size and length	Labeling indicates size and length	Equivalent
	Labeling indicates flow vs. pressure labels	Labeling indicates flow vs. pressure labels	Labeling indicates flow vs. pressure labels	N/A	Equivalent
	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Can be manipulated with gloved hand	N/A	Equivalent
Design	Designed to be placed in the ventricle of the brain and under the scalp	Designed to be placed under the scalp (valve component only)	Designed to be placed temporarily on the scalp and on the clavicle	Designed to be placed in the ventricle of the brain (ventricular catheter only)	Equivalent
	flexible catheter to remain implanted in the brain	N/A	N/A	flexible catheter to remain implanted in the brain	Equivalent
	Series of holes at proximal end of the catheter for fluid movement	N/A	N/A	Series of holes at proximal end of the catheter for fluid movement	Equivalent
	20 flow holes	N/A	N/A	24 flow holes	Equivalent
	4 lines of 5 holes	N/A	N/A	3 lines of 8 holes	Equivalent
	bullet shaped tip	N/A	N/A	bullet shaped tip	Equivalent
	A single relief membrane distal to the proximal inlet holes of the catheter to open at a threshold pressure for restoration of fluid	N/A	N/A	N/A	Equivalent The relief membrane is equivalent to inlet holes since it provides fluid entry

	SUBJECT DEVICE Alcyone Alivio System (K172006)	PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)	REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)	REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)	Equivalence Comparison
	movement				into catheter when opened. The relief membrane can only be opened if the inlet holes are blocked.
	Length from proximal tip to the most distal holes and relief membrane is 0.720"	N/A	N/A	Length from proximal tip to the most distal holes is 0.720"	Equivalent
	Catheter is not impregnated with antimicrobial agents.	N/A	N/A	Catheter is not impregnated with antimicrobial agents.	Equivalent
	Barium sulfate-filled catheter	N/A	N/A	Barium sulfate-filled catheter	Equivalent
	Inner diameter of catheter: 0.050"	N/A	N/A	Inner diameter of catheter: 0.055" or 0.050"	Equivalent
	Outer diameter of catheter: 0.100"	N/A	N/A	Outer diameter of catheter: 0.106" or 0.100"	Equivalent
	Catheter length: 15cm initially (other common lengths may be offered)	N/A	N/A	Catheter length: 14, 15, 23 cm	Equivalent
	Length markings: 1 dot at 10cm and 2 dots at 15cm	N/A	N/A	1 dot at 10cm and 2 dots at 15cm	Equivalent
	Stylet for catheter insertion	N/A	N/A	Stylet for catheter insertion	Equivalent
	Reservoir (Rickham or comparable). Not tested or made as a claim.	Reservoir (Rickham or comparable). Not tested or made as a claim.	N/A	Can be used in conjunction with a Rickham or other reservoirs	Equivalent
	Right angle clip compatible (not provided)	N/A	N/A	Right angle clip	Equivalent
	Flushing - unidirectional control by occluders	Flushing - bidirectional control done by occluders	Vibrational pressure, direction unknown	N/A	Equivalent
	Flush direction only towards ventricle (proximal)	Flushing directions toward ventricle (proximal) or drainage (distal)	Unknown	N/A	Equivalent
	Increases flow through a non-flowing catheter	Use of retrograde flush or shunt tap to increase flow possible, but not a claim	Increases flow through a non-flowing catheter	N/A	Equivalent
	Flow regulation (allows passive flow for use in-line with a one-way check valve to regulate flow in system)	One way check valve to regulate flow in system	Does not affect flow regulation	N/A	Equivalent
	Fluid filled reservoir	0.25 mL fluid filled	N/A	N/A	Equivalent

	SUBJECT DEVICE Alcyone Alivio System (K172006)	PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)	REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)	REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)	Equivalence Comparison
	less than 0.5 mL	reservoir			
	Barb fittings for connection to ventricular catheter and shunt valve	Barb fittings for connection to ventricular catheter	N/A	N/A	Equivalent
	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	N/A	N/A	Equivalent
	Inner channel diameter: greater than 1mm	Inner channel diameter unknown	N/A	N/A	Equivalent Passive flow channel diameter meets ISO 7197:2006
	40mm in length 17mm in width 10mm height	32mm in length 16mm in width 8mm in height	N/A	N/A	Equivalent to predicate and size/dimension acceptable to user per human factors studies conducted
	Reservoir and shunt accessories withstand use forces	Reservoir withstands flushing and shunt taps.	Reservoir and shunt accessories withstand vibrations	N/A	Equivalent
	Can be used with dimensionally compatible shunt system components	Can be used with dimensionally compatible shunt system components	Can be used with dimensionally compatible shunt system components	Can be used with dimensionally compatible shunt system components	Equivalent
	Low profile for implantation under the scalp	Low profile for implantation under the scalp	N/A	N/A	Equivalent
	Soft and flexible outer housing	Soft and flexible outer housing	N/A	N/A	Equivalent
	Rigid sections in the housing to seat valves	Rigid sections in the housing	N/A	N/A	Equivalent
	Occluders (distal drainage channel is occluded during flush)	Distal and proximal occluders	Unknown (likely N/A)	N/A	Equivalent
	Printing to indicate direction of flow and position	Printing to indicate direction of flow and position	N/A	N/A	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 when proximal occluder is activated - force within system and limited by fixed reservoir volume.	Retrograde vibrations into ventricular catheter - force in system and to patient unknown	N/A	Equivalent
	One way flow between the reservoir and ventricular catheter when device is	One way flow between reservoir and catheters when occluder is pressed	N/A	N/A	Equivalent

	SUBJECT DEVICE Alcyone Alivio System (K172006)	PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)	REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)	REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)	Equivalence Comparison
	pumped	and reservoir is pumped			
	Reservoir refills after pumping	Reservoir refills after pumping	Reservoir refills after vibrations	N/A	Equivalent
	Normal shunt function resumes after pumping	Normal shunt function resumes after pumping	Normal shunt function resumes after vibrations	N/A	Equivalent
	Catheter diverts fluid from ventricle	Catheter diverts fluid from ventricle (through check valve)	N/A	Catheter diverts fluid from ventricle	Equivalent
	Relief membrane remains open after activating	Inlet holes are intended to remain patent to provide fluid path.	N/A	Inlet holes are intended to remain patent to provide fluid path.	Equivalent Provides same fluid path into catheter as open inlet holes
Materials	Ventricular Catheter: silicone with BaSO4 filler, relief membrane silicone	N/A	N/A	Ventricular Catheter: BaSO4 filled silicone elastomer	Equivalent
	Valves: silicone	Valves: silicone	N/A	N/A	Equivalent
	Dome/outer housing: silicone	Outer housing: silicone	N/A	N/A	Equivalent
	N/A	Needle guard: polypropylene	N/A	N/A	N/A
	N/A	N/A	Micro-pumper: Polyurethane plastic	N/A	N/A
Biocompatibility	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Tissue contact tested per ISO 10993: Biological Evaluation of Medical Devices	Equivalent
	Non-pyrogenic	Non-pyrogenic	N/A	Non-pyrogenic	Equivalent
Compatibility with environment and other devices	Safe in 1.5T MRI environment	Safe in 1.5T MRI environment	N/A	Safe in 1.5T MRI environment	Equivalent
	Safe in an x-ray environment	Safe in an x-ray environment	No radiation	Safe in an x-ray environment	Equivalent
	Compatible with current shunt systems and accessories	Compatible with current shunt systems and accessories	Compatible with current shunt systems and accessories	Compatible with current shunt systems and accessories	Equivalent
	Compatible with long term CSF contact and saline	Compatible with long term CSF contact and saline	N/A	Compatible with long term CSF contact and saline	Equivalent
Radiopacity	BaSO4 filled silicone elastomer	BaSO4 filled silicone elastomer	N/A	BaSO4 filled silicone elastomer	N/A
Sterility	Terminally sterilized for 10^{-6} SAL with no damage to system components. Validated per ANSI/AAMI/ISO 11137-2; Sterilization	Terminally sterilized for 10^{-6} SAL with no damage to system components. Validated per recognized	None	Terminally sterilized for 10^{-6} SAL with no damage to system components. Validated per recognized	Equivalent

	SUBJECT DEVICE Alcyone Alivio System (K172006)	PRIMARY PREDICATE Integra Neurosciences Contour-Flex Valve and Shunt System (K033698)	REFERENCE PREDICATE NeuroDx Development, LLC ShuntCheck III (K123554)	REFERENCE PREDICATE Codman Medos Ventricular Catheter (K944222)	Equivalence Comparison
	of health care products - Radiation	sterilization standard.		sterilization standard.	
Electrical Safety	N/A	N/A	IEC 60601 Tested	N/A	N/A
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	Micro-Pumper generates less ventricular suction than manual shunt pumping, no valve damage or alteration	N/A	Equivalent
Chemical Safety	Saline, CSF	Saline, CSF	Saline, CSF	Saline, CSF	Equivalent
MRI Compatibility	MR Safe	MR Safe	Not MR Safe	MR Safe	Equivalent
Radiation Safety	X-ray Safe	X-ray Safe	No Radiation	X-ray Safe	Equivalent
Packaging	Packaging maintains sterility and protects device. Tray, pouch, box. Catheter and flusher packaged together.	Packaging maintains sterility and protects device. Tray, pouch, box. Multiple components can be packaged together.	Unknown	Packaging maintains sterility and protects device. Tray, pouch, box. Multiple components can be packaged together.	Equivalent
Shelf Life	Labeled shelf life (expiation) will be based on real time and accelerated aging shelf life studies 1-3 years.	Labeled shelf life 1-3 years.	Unknown	Labeled shelf life 1-3 years.	Equivalent

Rx or OTC

The Alivio System is an Rx prescription device per 21 CFR Part 801, Subpart D.

Performance Data

Preclinical and clinical tests were conducted on the Alivio System 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, comparative usability testing in animals, human factors evaluations in a simulated clinical use model per the available guidance, and clinical testing. The design, testing, and technical information provided for the Alivio System 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
Biocompatibility	Cytotoxicity (MEM and NRU): Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-5, "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity"	Results support that the Alivio System is non-cytotoxic.

Test	Test Method Summary	Results and Conclusions
	Sensitization (Kligman): Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-10, "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"	Results support that the Alivio System is a non-sensitizer.
	Intracutaneous Reactivity: Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-10, "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"	Results support that the Alivio System is a non-irritant.
	Systemic Toxicity: Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-11, "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"	Results support that the Alivio System is non-toxic.
	Pyrogenicity (Material Mediated): Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-11, "Biological evaluation of medical devices - Part 11: Tests for systemic toxicity"	Results support that the Alivio System is non-pyrogenic.
	Genotoxicity (Ames Mutagenicity): Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-3, "Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity"	Results support that the Alivio System is non-mutagenic.
	Hemocompatibility (Direct and Indirect): Conducted Testing for CSF contacting permanent implant device in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-4, "Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood"	Results support that the Alivio System is non-hemolytic.
	Exhaustive Chemical Characterization: Conducted Testing in accordance with ISO 10993-1 Biological Evaluation of Medical Devices and FDA Guidance, Use of International Standard ISO 10993-18, "Biological evaluation of medical devices - Part 18: Chemical characterization of materials" and International Standard ISO 10993-17, "Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances"	Results support that Alivio System is non-carcinogenic, non-mutagenic, and non-toxic.
	Metals Analysis: Conducted Testing in accordance with ASTM F647 Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	Results support that the Alivio System is in compliance with the allowable extract levels outlined in Section 5.2 and Appendix X2.5 of ASTM F647.
Packaging	Conducted Testing in accordance with ISTA-2A Partial Simulation Performance Tests, ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test) and ASTM F88-09 Standard Test Method for Seal Strength of	All testing passed.

Test	Test Method Summary	Results and Conclusions
	Flexible Barrier Materials	
Sterilization	Conducted Testing in accordance with ANSI/AAMI/ISO 11137-1:2006 Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product, ANSI/AAMI/ISO 11137-2:2013 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose, and ANSI/AAMI/ISO 11137-3:2006 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects	Terminal sterilization validation testing supports a 10-6 SAL.
Pyrogenicity	LAL testing was validated in accordance with the applicable FDA's Guidelines (Guideline on Validation of the Limulus Amebocyte Lysate Test As An End-Product Endotoxin Test for Human And Animal Parenteral Drugs, Biological Products, and Medical Devices - 1997) and recognized standards (USP Endotoxin Reference Standard) for Bacterial Endotoxin (LAL) Validation using the Kinetic-QLC Test Method.	This test validates the method for measuring the endotoxin levels of he finished device per ANSI/AAMI ST72:2011 Bacterial endotoxins – test methodologies, routine monitoring, and alternatives to batch testing. All units tested met the criteria of less than 2.15 EU/device (0.06 EU/mL).
Shelf Life	Accelerated and Real-time Aging was conducted on the device and packaging. Testing comparing devices and packaging at time 0 and the intended shelf life was conducted in accordance with applicable standards and the product specifications. Tests include visual/dimensional inspections, surface inspection, particulate testing, strength and reliability testing, and system performance testing.	Testing, including visual/dimensional inspections, particulate testing, surface inspection, mechanical and system performance testing comparing devices at time 0 and the intended shelf life. Results supports expiration dating on the labeling.
Pressure Leak Tests and Pressure Flow Characteristics Test	Conducted Testing in accordance to Sections 4.4 and 4.6 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 corresponding pressure profiles were recorded and plotted as graphs as per ASTM F 647-94(2014), Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application, Sections A 2.8.1.1 and A2.8.1.2 to evaluate and compare the pressure-flow characteristics of the Alivio Catheter to Predicate Catheter.	All devices passed the pressure leak test and the appropriate pressure flow characteristic graph is provided in the device labeling.
Durability and System Level Functional Test	Conducted Testing in accordance to ASTM F 647-94(2014), Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device.
Flusher and Catheter Dynamic Break Strength Test	Conducted Testing for the ventricular catheter and flusher components in accordance to Section 4.9 of ISO 7197:2006 (E), Neurosurgical Implants - Sterile, single-use hydrocephalus shunts to assess dynamic breaking strength.	All results met acceptance criteria per protocol and applicable standards. During this test, no component ruptured or broke.
Flusher and Catheter Tensile Strength Test	Conducted Testing for the ventricular catheter and flusher to evaluate the bond/tensile strength of these components in accordance with ASTM F 647-94(2014) "Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device.
Flusher Pressure Handling Test	Conducted Testing for flusher in accordance to Section 4.11 of ISO 7197:2006 (E), Neurosurgical Implants - Sterile, single-use hydrocephalus shunts	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended

Test	Test Method Summary	Results and Conclusions
	to assess dynamic breaking strength.	use and is substantially equivalent to the predicate device.
Alivio Cartridge Performance Test	This test measures the AF cartridge cracking pressure to demonstrate compliance of AF Cartridge with requirements for cartridge performance (flush pressure).	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device.
Catheter Bond Pressure Test	Catheters were subjected to pressure testing at a minimum of twice the maximum relief membrane opening pressure specification.	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use.
Alivio Flusher Reliability Test	Testing was conducted to verify the reliability of the Alivio Flusher to be able to flush during its expected useful life. Testing included an assessment of any mechanical damage and the ability to flush with acceptable pressure and volume output.	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device.
MR Safety	Conducted Assessment in accordance ASTM F647-94(2014), “Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application”, Section 6.1.3 “Magnetic Resonance Imaging (MRI) Compatibility”	All implanted Alivio System materials/components comply with the FDA guidance to label “MR Safe” in all MR environments.
Alivio System Imaging	The devices were imaged using X-ray to demonstrate compliance with requirements for imaging per ASTM F 647-94(2014) and ISO 7197:2006.	All results met acceptance criteria and demonstrate that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device.
Occlusion Flushing Performance	Devices were occluded with blood and other substances to clinically simulate proximal catheter occlusions (blocked proximal catheter inlet holes) in the Alivio System and predicate device. These devices were then tested to evaluate ability of the device’s retrograde flush to unblock inlet holes.	Comparative testing demonstrated that the Alivio System performance is suitable for its intended use and is substantially equivalent to the predicate device. Flushing of the Alivio System was able to restore flow in the ventricular catheter with simulated blocked inlet holes.
Comparative Performance Testing in Animals	Pilot animal study (N=1 evaluated at an acute timepoint) was conducted in two parts to demonstrate that the Alivio System meets its functional requirements and was tested in comparison to the predicate to demonstrate that the Alivio System does not raise new questions of safety and efficacy and is substantially equivalent to the predicate.	All results met the acceptance criteria and demonstrated that the Alivio System meets its performance criteria. No significant difference of histological analysis of tissue between Alivio System and predicate was found. Testing demonstrated that the Alivio System does not raise any new questions of safety and efficacy and is substantially equivalent to the predicate.
	Pilot animal study (N=2 evaluated at subacute and acute timepoints) was conducted to demonstrate that the Alivio System meets its functional requirements and was tested in comparison to the predicate to demonstrate that the Alivio System does not raise new questions of safety and efficacy and is substantially equivalent to the predicate.	All results met the acceptance criteria and demonstrated that the Alivio System meets its performance criteria. No significant difference of histological analysis of tissue between Alivio System and predicate was found. Testing demonstrated that the Alivio System does not raise any new questions of safety and efficacy and is substantially equivalent to the predicate.
	Pilot animal study (N=2 evaluated at acute timepoints) comparing the Alivio System with the predicate was conducted to demonstrate that the differences in technology do not raise new questions of safety and is substantially equivalent to the predicates.	Results demonstrated that a small animal model was not suitable for comparative testing of the Alivio System and the predicate. However, there was no significant difference of histological analysis of tissue between Alivio System and predicates.
	Animal study (N=11 evaluated at subacute	All results, including performance as well

Test	Test Method Summary	Results and Conclusions
	timepoints) comparing the Alivio System with the predicate was conducted to demonstrate that the Alivio System meets its functional requirements, the differences in technology do not raise new questions of safety, and is substantially equivalent to the predicates. Testing was conducted in conformance to FDA 21 CFR, Part 58-Good Laboratory Practice for Nonclinical Studies.	as comparative CSF and histopathology analysis, met acceptance criteria. Testing demonstrated that the Alivio System does not raise any new questions of safety and efficacy and is substantially equivalent to the predicate.
	Animal study (N=6 evaluated at acute timepoints) comparing the Alivio System with the predicate was conducted to demonstrate that the differences in technology do not raise new questions of safety and is substantially equivalent to the predicates. Testing was conducted in conformance to FDA 21 CFR, Part 58-Good Laboratory Practice for Nonclinical Studies.	No significant difference of histological analysis of tissue between Alivio System and predicate was found. Testing demonstrated that the Alivio System does not raise any new questions of safety and efficacy and is substantially equivalent to the predicate.
Usability and human factors testing	Testing of the Alivio System in animal and clinical simulation bench models was conducted to evaluate ease of preparation, implantation, and use for its intended use according to its labeling was 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.	Alivio System is deemed to meet its specifications for its intended use and is substantially equivalent to the predicate devices. 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. These data demonstrate that the minor technological differences do not raise new types of safety and efficacy concerns as evaluated by 24 neurosurgeons (intended users) of varying experience in numerous simulated clinical uses of the Alivio System. The Alivio System functions as components of a CSF Shunt System and is substantially equivalent to its predicate devices.
Alivio Flusher Clinical Study	The Alivio Flusher was evaluated in a clinical setting to demonstrating functional safety of the Alivio flusher in patients undergoing shunt revision surgery. (NCT02651337)	The outcomes on 4 patients treated at the time of submission met the criteria for success outlined in the protocol. All users were able to perform the primary steps needed to use the Alivio Flusher for its intended use and use environment. No safety issues associated with the device were observed. These results demonstrate that the Alivio Flusher could increase or restore flow in occluded or sluggish flowing catheters.

Manufacturing and traceability of devices tested were conducted in accordance with 21 CFR Part 820 Good Manufacturing Practices and BS EN ISO 13485:2003 Medical Devices – Quality Management Systems. In all instances, the Alivio System functioned as intended and results observed were as expected. These test results confirm that Alivio System complies with the recognized standards, meets the design specifications and performance requirements for the intended use, and is substantially equivalent to the predicate.

Substantial Equivalence

The Alivio System is substantially equivalent to the primary predicate the Integra Contour-Flex™ Valve and Shunt System (K033698), and reference predicates the NeuroDX Development ShuntCheck III (K123554), and the Codman Medos Ventricular Catheter (K944222). The Alivio System and its predicate devices share the same Product Code and classification as components of a CSF Shunt System. The Alivio System has the same intended use as the primary predicate device and equivalent indications for use. The Alivio System also has a

very similar design and technological characteristics to the predicate devices. Minor differences in technological characteristics do not raise new questions of safety and efficacy when all listed warnings and cautions are followed.

The key technological difference is that the Alivio Ventricular Catheter has an added relief (slit) membrane that may be opened by the flusher component to restore CSF flow in a suspected non-flowing shunt. Similar to the predicate Integra Contour-Flex Valve that can produce a retrograde flush to unblock suspected blocked inlet holes in a ventricular catheter; when manually activated by the neurosurgeon, the flusher component can non-invasively produce a retrograde flush to either unblock suspected blocked inlet holes or open the relief membrane in the Alivio Ventricular Catheter.

Similar to the ShuntCheck reference predicate, the Alivio System has features designed to restore flow in a suspected non-flowing shunt. They differ slightly in technological characteristics in that the ShuntCheck predicate uses a micropumper to create vibrational pumping of the reservoir, while the Alivio System employs manual proximal pumping of the reservoir by the neurosurgeon, similar to the primary predicate Integra Contour-Flex Valve predicate.

The Flusher does not regulate flow in the shunt system. Rather it allows for passive flow of fluid from the Alivio Ventricular Catheter to a flow regulating valve (connected distally in line with the flusher) when not manually activated by the neurosurgeon to produce a retrograde flush. The Alivio Flusher is compatible with all shunt valves with standard barbed connections, but has only been tested with the Integra Contour-Flex Valve predicate device. During passive flow, fluid from the ventricular catheter flows freely, without restriction through the passive flow channel of the Flusher. Use of the Alivio Flusher does not inhibit the function of the flow regulating valve.

The results from preclinical and clinical evaluations demonstrate that the technological and performance characteristics of the Alivio System meet defined design requirements and can perform in a manner equivalent to devices currently on the market used for its intended/indicated use. Performance data demonstrate that the Alivio System performs as intended and is substantially equivalent to its predicate(s).

Conclusions

The data and information presented within this submission support a determination of substantial equivalence to the predicate(s) listed above, and therefore market clearance of the subject Alivio System for its intended use. This conclusion is based upon the device equivalence in design, materials technological characteristics, principles of operation, and indications for use.