DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 16, 2015

Alcyone Lifesciences, Inc.
% Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K150660
Trade/Device Name: Alcyone MEMS Cannula (AMC) System
Regulation Number: 21 CFR 882.4060
Regulation Name: Ventricular Cannula
Regulatory Class: Class I
Product Code: HCD
Dated: March 4, 2015
Received: March 13, 2015

Dear Mr. Job:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150660

Device Name
Alcyone MEMS Cannula (AMC) System

Indications for Use *(Describe)*
The Alcyone MEMS Cannula (AMC) System consisting of the AMC and the AMC Extension Line Set, is intended for injection of Cytarabine (cytosine arabinoside) or removal of cerebrospinal fluid (CSF) from the ventricles of the brain during intracranial procedures. The AMC System is not intended for implant. The device is intended for "single patient use only."

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
Alcyone Lifesciences, Inc.'s MEMS Cannula (AMC)

Alcyone Lifesciences, Inc.
130 John Street, Boot Canal Mill Building, C-2
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Phone: 513-236-0857
Facsimile: 513-898-2106

Contact Person: Elsa Chi Abruzzo, RAC, FRAPS
Date Prepared: April 10, 2015

Alcyone Lifesciences, Inc.

Trade Name:	Alcyone MEMS Cannula (AMC) System
Common or Usual Name	Ventricular Cannula
Classification Name	Ventricular Cannula
Classification:	Class I
Product Code and Regulation:	HCD, 21 CFR 882.4060
Classification Panel:	Neurology
Predicate Device:	K102101 SurgiVision, Inc. MR Compatible Ventricular Cannula (a.k.a., MRI Interventions Inc., SmartFlow Ventricular Cannula)

Intended Use / Indications for Use

The Alcyone MEMS Cannula (AMC) System consisting of the AMC and the AMC Extension Line Set, is intended for injection of Cytarabine (cytosine arabinoside) or removal of cerebrospinal fluid (CSF) from the ventricles of the brain during intracranial procedures. The AMC System is not intended for implant. The device is intended for "single patient use only."

Description of Device

The AMC System is comprised of the AMC and its Extension Line sets. The AMC is a rigid cannula comprised of two independent channels. The fluid lumens are protected inside a 25cm rigid ceramic cannula, which transitions (steps-down) to a micro-tip. The micro-tip has two independent outlets at the tip that face sideways, designed to prevent plugging during insertion into the brain. The proximal end of the rigid cannula consists of a Y-connector with standard female luers that allow connection to each independent channel. AMC Extension Line Sets with standard male/female luers must be used with the AMC to connect the AMC to an infusion pump. The AMC must be used with a support structure (e.g. a stereotactic guide) to provide support and control during insertion. A safety-sheath, as with the predicate, and depth-stop, for user convenience, are provided on the AMC for this purpose.

Technological Characteristics
The AMC is equivalent in technological characteristics to its predicate device.

	AMC System Subject 510 (k)	SurgiVision Ventricular Cannula (VC) K102101	Discussion
Classification	21 CFR 882.4060	21 CFR 882.4060	Equivalent to Predicate
Product Code	HCD	HCD	Equivalent to Predicate
Indications for Use/ Intended Use	The Alcyone MEMS Cannula (AMC) System consisting of the AMC and the AMC Extension Line Set, is intended for injection of Cytarabine (cytosine arabinoside) or removal of cerebrospinal fluid (CSF) from the ventricles of the brain during intracranial procedures. The AMC System is not intended for implant. The device is intended for "single patient use only."	The MR Compatible Ventricular Cannula is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."	Equivalent to Predicate.
How Used	Gains access to brain ventricles	Gains access to brain ventricles	Equivalent to Predicate
	Allows injection of Cytarabine into the ventricles	Allows injection of Cytarabine into the ventricles	Equivalent to Predicate
	Allows aspiration of CSF from the ventricles	Allows aspiration of CSF from the ventricles	Equivalent to Predicate.
	Not implantable	Not implantable	Equivalent to Predicate
	Single use	Single use	Equivalent to Predicate
Target Population	Pt. s needing injection of Cytarabine to the brain ventricles or aspiration of CSF from the ventricles	Pt. s needing injection of Cytarabine to the brain ventricles or aspiration of CSF from the ventricles	Equivalent to Predicate
Anatomical Sites	Brain ventricle	Brain ventricle	Equivalent to Predicate
Where Used	Operating Room or MR Suite	Operating Room or MR Suite	Equivalent to Predicate
	MRI/Diagnostic / Surgical Room	MRI/Diagnostic / Surgical Room	Equivalent to Predicate
Energy Used	N/A	N/A	Equivalent to Predicate
Human Factors	Labeling indicates size and length	Labeling indicates size and length	Equivalent to Predicate.
	Labeling indicates flowrates	Labeling indicates flowrates	Equivalent to Predicate.
	Can be manipulated with gloved hand	Can be manipulated with gloved hand	Equivalent to Predicate

	AMC System Subject 510 (k)	SurgiVision Ventricular Cannula (VC) K102101	Discussion
Design	Designed to be placed through a prepared opening through the skull and the Dura into the brain ventricle	Designed to be placed through a prepared opening through the skull and the Dura into the brain ventricle	Equivalent to Predicate
	Compatible with stereotactic guidance systems equipped with adapters possessing a 2.6mm inner diameter.	Compatible with MRI Interventions Stereotactic Frame	Equivalent to Predicate
	Rigid section to enter the brain	Rigid section to enter the brain	Equivalent to Predicate
	Straight section to enter the brain	Straight section to enter the brain	Equivalent to Predicate
	Two holes at distal end for fluid movement	Hole at distal end for fluid movement	Equivalent to Predicate. One hole per fluid channel.
Design	Distal holes	Distal holes	Equivalent to Predicate. Distal holes openings are towards the side designed to prevent tissue blockage during insertion.
	Body markings designed to facilitate determination of insertion depth	No marking on body of device	Equivalent to Predicate. Length marking on body to help user determine depth of insertion. Length markings are common in these devices to aid the user in positioning.
	Length of rigid section 9"	Length of rigid section 10.5" (30cm)	Equivalent to Predicate. Does not change user interface or utility. This is within the range of cleared ventricular cannulas.
	Two lumens. Inside diameter of each lumen in body: 0.010" (.25mm). Inside cross-section of each lumen in tip: 0.002"x0.001" (.052 x.03mm)	One Lumen: Inside diameter: 0.008" (0.2mm) to 0.021" (0.53mm)	Equivalent to Predicate. Both devices are moving fluids and their different inside/outside diameters result in different flow rates. This is within the range of cleared ventricular cannulas.
	Outside diameter: 0.65" (1.6mm)	Outside diameter: 0.65" (1.6mm) and 0.80" (2.0mm)	Equivalent to Predicate
	No stylet	No stylet	Equivalent to Predicate
	Lumen extension (10 foot) allows remote (end of scanner bore) injection/aspiration	Lumen extension (3 foot) allows remote (end of scanner bore) injection/aspiration	Equivalent to Predicate. Extensions allow for MR compatibility.

	AMC System Subject 510 (k)	SurgiVision Ventricular Cannula (VC) K102101	Discussion
Design	Lumen extension (25 foot) allows remote (outside of scanner 5 gauss) injection/aspiration using a non-MRI safe pump	Lumen extension (9 foot) allows remote (outside of scanner 5 gauss) injection/aspiration using a non-MRI safe pump	Equivalent to Predicate. Extensions allow for MR compatibility.
	Tip Sheath	Tip Sheath	Equivalent to Predicate
	Depth-stop bushing to facilitated setting of insertion depth	No depth stop	Equivalent to Predicate. With the predicate device the user uses generic stops when using Predicate with various frames. AMC provides a stop for user convenience.
	Standard luer	Standard luer	Equivalent to Predicate.
	Compatible with standard syringe pumps for infusion.	Compatible with syringe pumps for infusion.	Equivalent to Predicate
	Translucent luers	Translucent luers	Equivalent to Predicate.
Performance	Sufficiently rigid to pass through brain tissue without additional support.	Sufficiently rigid to pass through brain tissue without additional support.	Equivalent to Predicate
	Flow rate of: 3.0mL/hr. (1.5mL/hr. per channel) at <25psi internal pressure per channel	Flow rate of: 0.3ml/hr. (0.008" ID) to 25ml/hr. (0.021" ID) at 0.7psi	Equivalent to Predicate. Both devices are moving fluids, and the different flow rates results only from their different diameters. Pressures listed are internal to the system.
	Aspiration rate of: 2.4mL/hr. (1.2mL/hr. per channel) using an air vacuum of 10mL from a syringe.	Aspiration rate of: 0.1ml/hr. (0.008" ID) to 8.7ml/hr. (0.021" ID)	Equivalent to Predicate. Both devices are moving fluids, and the different flow rates results only from their different diameters.
Materials	Rigid body: Ceramic body Silicon tip	Rigid body: Ceramic Polymer Tip	Equivalent to Predicate. Both devices provide a rigid MRI compatible material for the body. Both devices have a step down design to a smaller tip.
Materials	Through lumen: Polymer covered silica Silicon	Through lumen: Polymer covered silica	Equivalent to Predicate. Both devices have a continuous fluid pathway and are MRI compatible and biocompatible.
	Detachable lumen extensions: Polymer	Non-detachable lumen extensions: Polymer coater silica	Equivalent to Predicate. Both devices have a continuous fluid pathway

	AMC System Subject 510 (k)	SurgiVision Ventricular Cannula (VC) K102101	Discussion
			and are MRI compatible and biocompatible.
	Proximal connector: Female luer connection	Proximal connector: Female luer connection	Equivalent to Predicate.
Biocompatibility	Limited exposure device, < 24 hours (Not implantable).	Limited exposure device, < 24 hours (Not implantable).	Equivalent to Predicate per ISO 10993: Biological Evaluation of Medical Devices.
	Non-pyrogenic	Non-pyrogenic	Equivalent to Predicate. Meets USP criteria for type of contact.
Compatibility with environment and other devices	Safe in 1.5T and 3T MRI environment	Safe in 1.5T MRI environment	Equivalent to Predicate
	Female luer connector on proximal end fits all male luer connections (e.g. Syringe tips)	Female luer connector on proximal end fits all male luer connections (e.g. Syringe tips)	Equivalent to Predicate
	Compatible with Stereotactic Frames with 2.6mm adapter	Compatible with MRI Interventions Stereotactic Frame	Equivalent to Predicate.
Sterility	10^{-6} SAL	10^{-6} SAL	Equivalent to Predicate per ANSI/AAMI/ISO 11137-2; Sterilization of health care products – Radiation.
Electrical Safety	N/A	N/A	N/A
Mechanical Safety	N/A	N/A	N/A
Chemical Safety	Lumen materials non-reactive to Cytarabine, Saline, CSF	Lumen materials non-reactive to Cytarabine, Saline, CSF	Equivalent to Predicate
	Silica lumen non-reactive	Silica lumen non-reactive	Equivalent to Predicate
Thermal Safety	MRI Safe. All brain contacting components tested in a 3.0T environment	MRI Safe. All brain contacting components tested in a 1.5T environment	Equivalent to Predicate
Radiation Safety	N/A	N/A	Equivalent to Predicate
Packaging	AMC - Tray, pouch, SBS box. Extension Lines - Pouch, Pouch, SBS box	Tray, pouch, box. Catheter with extension lines in same box.	Equivalent to Predicate
Shelf Life	1 year	Unknown. Assumed to be >1 year	Equivalent to Predicate

Rx or OTC
The AMC is an Rx prescription device per 21 CFR Part 801, Subpart D.

Performance Data

Bench and animal tests were conducted on the AMC 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 per the applicable standards and guidances included verification and validation testing, comparative usability testing in animals, and human factors evaluations in a simulated clinical use model. This is described in the summary tables below.

Summary of AMC System Performance Testing

Test	Test Method Summary	Results
AMC System Leak Pressure Testing Infusion Flow Testing Aspiration Testing	AMC and Extension Line Set (as a System) Line were tested for leak pressure and Infusion/ Aspiration flow. As applicable testing was done with room temperature water, body temperature Cytarabine (for infusion), and body temperature CSF (for aspiration).	Testing passed and results demonstrate the AMC System is safe for its intended use and substantially equivalent to the predicate device. <u>Leak Pressure</u> AMC and Extension line systems withstood pressure spikes with no leaks. <u>Infuse Flow Rate and Pressure</u> AMC System reached specified flow rate within the specified time and was capable of injecting fluid at it maximum flow rate. <u>Aspiration Rate</u> The AMC was capable of aspirating at its maximum aspiration rate.
Extension Line Set patency Testing Luer pull-off testing	Extension Line Sets were tested for line patency during bend and luer pull.	Testing passed and results demonstrate the Extension Line sets are safe for their intended use and substantially equivalent to the predicate device. <u>Extension Line Patency</u> Extension lines remained patent with a worst case expected bend radius <u>Luer Pull-off</u> All units were above the maximum luer pull force specification (worst case for clinical use plus safety factor).

Test	Test Method Summary	Results
AMC Brain insertion, removal, and lateral shift testing	Testing was conducted to test compliance of AMC with specified requirements for brain insertion, removal, and lateral shift strengths.	Testing passed and results demonstrate the AMC System is safe for its intended use and met its specifications. <u>Brain Insertion and Removal</u> AMC withstood insertion and removal into a bovine brain without breaking and detaching. <u>Brain Lateral Shift</u> AMC or AMC tip did not break or detach when laterally shifted in bovine brain tissue in any direction from the insertion location.
AMC tip-compression, bullet-nose pull-out, and y-connector pull-out testing	Testing was conducted to demonstrate compliance of AMC with requirements for tip compression strength, and pullout strengths of the bullet-nose and y-connector bond strengths.	Testing passed and results demonstrate the AMC System is safe for its intended use and met its specifications. <u>Axial Tip Compression Force</u> The AMC or AMC micro-tip withstood the acceptance criteria for axial compressive force based on clinically relevant forces with safety factor. <u>Pull-out strengths of bonds</u> The AMC withstood the acceptance criteria for minimum pull-out force based on clinically relevant forces with safety factor.
Magnetic Resonance (MR) Safe Testing	Testing was conducted to demonstrate MR Safety of the AMC and Extension Line Sets per the FDA guidance for MR Safety and Compatibility.	The AMC System is MR Safe for its intended use and substantially equivalent to the predicate device. <u>MR Compatibility</u> The AMC is MR Safe in 1.5 Tesla and 3Tesla magnets.

Test	Test Method Summary	Results
Cytarabine Infusion Compatibility	Testing was conducted to demonstrate compliance of AMC and Extension Lines with it specified requirements for Cytarabine concentration infusion (clinically relevant concentration). Testing evaluated effect of infusion of Cytarabine through the AMC System with respect to Cytarabine concentration post infusion and on device integrity after prolonged exposure to Cytarabine and acute infusion.	Testing passed and results demonstrate the AMC System is safe for its intended use and substantially equivalent to the predicate device. <u>Cytarabine Compatibility</u> The materials of the fluid path of the AMC are compatible with Cytarabine infusion of a specified clinically relevant concentration. There was no visible degradation or reduction in strength below specifications of the AMC and Extension lines after prolonged exposure or acute infusion of Cytarabine at its maximum permitted clinical concentration and durations. There was no change in Cytarabine concentration post infusion.
Transit Testing (Packaging Qualification)	Testing was conducted to demonstrate compliance of the AMC and Extension Lines with transit testing requirements per ISTA-2A.	Testing passed and results demonstrate that the AMC System packaging meets its functionality requirements and the integrity of the package as a sterile barrier was maintained after conducting actual or simulated Transportation Testing Conditions.
Accelerated Aging	Protocol defines the methods and materials to conduct accelerated aging of AMC and Extension Lines and packaging materials	Testing demonstrates that the AMC System is safe for its labeled expiration dating and substantially equivalent to the predicate device.
Biocompatibility	Testing was conducted to demonstrate compliance of the AMC and Extension Lines with ISO 10993 biocompatibility requirements.	All tissue contacting materials used in the AMC System are biocompatible per ISO 10993 –Biological evaluation of Medical Devices, Externally Communicating Device - Tissue contact, limited duration A < 24 hours. The following tests were done: • Cytotoxicity (MEM and NRU Elution) • Systemic Toxicity • Intracutaneous Reactivity • Sensitization (Klingman Maximization) • Hemocompatibility (Indirect) • Material Mediated Pyrogen

Test	Test Method Summary	Results
Sterilization Validation	Testing was conducted to demonstrate compliance of the AMC and Extension Lines with Sterilization Validation Standards to achieve a desired SAL.	Testing substantiates the use of 25 kGy as the minimum sterilization dose to achieve a sterility assurance level, SAL, of 10^{-6}, which is required for its intended use and is equivalent to the predicate device.
LAL Validation	Testing was conducted to demonstrate compliance of the AMC and Extension Lines with LAL requirements per the USP guidance for CNS contacting devices.	Testing demonstrated that all devices met an Endotoxin levels of <2.15 EU/device required for its intended use Per FDA Guidance 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 – 1997vand equivalent to the predicate device.

AMC System Animal Testing

Test	Test Method Summary	Results
AMC and Extension Line design validation and performance evaluation	Protocol defines the methods and materials to assess the conceptual design of the AMC and Extension Lines during the concept-development phase to meet its specifications per its intended use. N=7 Juvenile Yorkshire Pigs (Acute Study)	All results met acceptance criteria per protocol and applicable standards and indicate the AMC Systems is safe for its intended use and equivalent to the predicate device. This animal study demonstrated that the AMC System met its specifications as follows: • Insertion depth to target anatomies • Ease of use • Two independent channels function to their specifications for infusion and aspiration • Minimal/none occlusions during insertion • Compatible with stereotactic procedures • Minimal to no backflow and acceptable distribution of infusate

Test	Test Method Summary	Results
AMC and Extension Line design validation and performance evaluation	Protocol defines the methods and materials to assess the final design of the AMC and Extension Lines during the design development and design-freeze phase to meet its specifications per its intended use. N=4 Juvenile Yorkshire Pigs (Acute Study)	All results met acceptance criteria per protocol and applicable standards and indicate the AMC Systems is safe for its intended use and equivalent to the predicate device. (same as above)
AMC and Extension Line comparison with SurgiVision MR Compatible Ventricular Cannula K102101 (a.k.a. MRII SmartFlow Cannula)	Comparison of the AMC and Extension Lines with the SmartFlow (SF) cannula. Studies were done using Gadolinium (MR traces) infusions. Model – Juvenile Yorkshire Pig Test samples – AMC vs SF with Gadolinium (MR tracer). N=4 acute animals N=6 survival animals (survival for 4-weeks post infusion)	All results met acceptance criteria per protocol and applicable standards. The AMC performed substantially equivalent to the SF predicate device and according to its specifications.

AMC System Human Factors and Usability Testing Summary

Test	Test Method Summary	Results
AMC and Extension Lines User Validation testing and Human Factors Testing	Testing was conducted per the applicable standards and guidances and obtained user feedback in a simulated clinical use evaluation of the AMC and Extension Lines. N= 16 Users with repeat uses totaling 28 uses.	All results met acceptance criteria per protocol and applicable standards. The AMC performed safely for its intended use and as expected by the users per the AMC System instructions for use.

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 – Requirements for Regulatory Purposes. In all instances, the AMC functioned as intended and results observed were as expected. These test results confirm that AMC is safe, meets the design inputs, and raises no new safety or efficacy concerns. A summary of the AMC's design control activities with regards to risk analysis and verification and validation activities is provided in this 510 (k) submission.

Substantial Equivalence

The AMC has the same intended use/indications for use along with similar design, materials of construction, and similar technological characteristics as its predicate device. While there are technological differences between the AMC and the predicate, the SurgiVision MR Compatible Ventricular Cannula (such as two fluid channels in the AMC versus one in the predicate, different exit hole configuration, and dimensional differences); these differences do not raise new types of safety and effectiveness questions when all listed warnings and cautions are followed.

The results from preclinical evaluations, including comparative animal testing, human factors and usability studies in a simulated clinical use model; demonstrate that the technological and performance characteristics of the AMC 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 AMC performs as intended and is substantially equivalent to its predicate the SurgiVision MR Compatible Ventricular Cannula.

Conclusions

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