April 30, 2019

Balt USA, LLC
Nancy Xu
Regulatory Affairs Manager
29 Parker
Irvine, California 92618

Re: K183045
Device Name: ECLIPSE 2L
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN, DQY
Dated: March 29, 2019
Received: April 1, 2019

Dear Nancy Xu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for 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)*
K183045

Device Name
ECLIPSE 2L

Indications for Use *(Describe)*
The ECLIPSE 2L is indicated for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.

ECLIPSE 2L is indicated for use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as embolization coils.

ECLIPSE 2L is also indicated for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as DMSO based embolization materials, that have been approved for use in the neurovasculature and are compatible with the diameter of the ECLIPSE 2L.

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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ECLIPSE 2L
510(k) Summary

This 510(k) summary for ECLIPSE 2L is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendation outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]*, dated 28 July, 2014.

SUBMITTER [807.92(a)(1)]

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Date prepared:	April 29, 2019

DEVICE [807.92(a)(2)]

Name of Device:	ECLIPSE 2L
Common or Usual Name:	Occlusion Balloon Catheter
Classification Name:	Vascular Clamp Percutaneous Catheter
Product Code:	MJN DQY
Regulatory Class:	Class II
Submission Type:	Traditional 510(k)
Regulation Number:	21 C.F.R. 870.4450 21 C.F.R. 870.1250
Reviewing Product Branch:	Division of Neurological and Physical Medicine Devices (Office of Device Evaluation, CDRH)

PREDICATE DEVICE [807.92(a)(3)]

Scepter C/XC Occlusion Balloon Catheter (K121785)

REFERENCE DEVICE

HyperGlide and HyperForm Occlusion Balloons (K101570)

DEVICE DESCRIPTION [807.92(a)(4)]

ECLIPSE 2L balloon catheters are catheters with dual lumen arranged in a parallel configuration. The guidewire lumen or the working lumen is DMSO compatible and can be used for infusion/delivery of diagnostic and therapeutic devices. The inflation lumen is used for the inflation and deflation of the balloon. The inflation and deflation of the balloon can be achieved independently of the presence of the guidewire. ECLIPSE 2L balloon catheter is equipped with a non-detachable low inflation pressure super compliant balloon welded to the distal end of the catheter.

The ECLIPSE 2L balloon catheter incorporates 3-4 radiopaque markers. The radiopaque marker bands are located at the distal end of the working lumen and at either end of the balloon to facilitate fluoroscopic visualization during procedure. The short nose (SN) variant has an additional proximal marker located 3 cm from the distal tip of the catheter to aid in positioning detachable coils. The ECLIPSE 2L also has distal purge holes to purge air from the balloon prior to use. The catheter and the outer surface of the balloon is coated with hydrophilic coating to reduce friction and increase lubricity. An introducer sheath is provided with the device as an accessory.

INDICATIONS FOR USE [807.92(a)(5)]

The ECLIPSE 2L is indicated for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms.

ECLIPSE 2L is indicated for use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as embolization coils.

ECLIPSE 2L is also indicated for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as DMSO based embolization materials, that have been approved for use in the neurovasculature and are compatible with the diameter of the ECLIPSE 2L.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The technological characteristics of the ECLIPSE 2L is highly analogous to the technological characteristics of the Scepter C/XC Occlusion Balloon Catheter (K121785) and HyperGlide and HyperForm Occlusion Balloons (K101570). Substantial equivalence is determined based on the following similarities:

- similar intended use/indications for use
- Same principles of operation

- Same fundamental scientific technology
- Incorporate similar basic balloon catheter design
- Incorporate similar balloon catheter construction material

Table 1 comprises the comparison between ECLIPSE 2L (Subject Device), Scepter C/XC Occlusion Balloon Catheter (Predicate Device, K121785) and HyperGlide and HyperForm Occlusion Balloons (Reference Device, K101570).

Table 1: Predicate Device, Reference Device vs. Subject Device Comparison

Feature	Scepter C/XC Occlusion Balloon Catheter [PREDICATE DEVICE] [K121785]	HyperGlide and HyperForm Occlusion Balloons [REFERENCE DEVICE] [K101570]	ECLIPSE 2L [SUBJECT DEVICE]
Product Code	MJN DQY	MJN	Same as Predicate Device
Regulatory Class	Class II	Class II	Same as Predicate Device and Reference Device
Regulation Number	21 CFR 870.4450 21 CFR 870.1250	21 CFR 870.4450	Same as Predicate Device
Regulation Name	Vascular Clamp Percutaneous Catheter	Vascular Clamp	Same as Predicate Device
Generic Name	Occlusion Balloon Catheter	Occlusion Balloon Catheter	Same as Predicate Device and Reference Device

Indications for Use Statement	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms. For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials. For neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the diameter of the Scepter C/XC Balloon Catheter.	The ev3 Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the Occlusion Balloon Catheters may also be used in balloon-assisted embolization of intracranial aneurysms.	The ECLIPSE 2L is indicated for use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and for balloon assisted embolization of intracranial aneurysms. ECLIPSE 2L is indicated for use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as embolization coils. ECLIPSE 2L is also indicated for neurovascular use for the infusion of diagnostic agents, such as contrast media, and therapeutic devices, such as DMSO based embolization materials, that have been approved for use in the neurovasculature and are compatible with the diameter of the ECLIPSE 2L.

Feature	Scepter C/XC Occlusion Balloon Catheter [PREDICATE DEVICE] [K121785]	HyperGlide and HyperForm Occlusion Balloons [REFERENCE DEVICE] [K101570]	ECLIPSE 2L [SUBJECT DEVICE]
Intended Use	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow and also offers balloon assisted embolization of intracranial aneurysms. For general intravascular use, including the peripheral and neurovasculature, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.	The ev3 Occlusion Balloon Catheters are intended for use in the peripheral and neuro vasculature wherever temporary occlusion is desired as well as for balloon-assisted embolization of intracranial aneurysms.	Same as Predicate Device.

Lumen Configuration	Dual coaxial lumen	Single lumen	Dual Lumen (parallel)
Guidewire Lumen Inner Diameter	0.0165”	Not Listed	0.0161” (guidewire lumen inner diameter)
Outer Diameter	2.6-2.8F	Not Listed	Major OD: 3.3 F (1.1mm) Minor OD: 2.7 F (0.9mm)
Balloon Diameter	4 mm	3-7 mm	6 mm
Balloon Length	10-20 mm	7-30 mm	7-20 mm
Material	Polyether block amide, polyolefin, stainless steel, PTFE, polyurethane elastomeric alloy, Pt alloy, polypropylene	Not Listed	Polyamide, Polyether Block Amide, Estane, PTFE, TPE, Gold
Introducer Sheath	Yes	Not Listed	Same as Predicate Device
Shaping Mandrel	Yes	Not Listed	No
Distal Tip Shaping	Yes	Not Listed	No
Guidewire Compatibility	0.014” wire or smaller	0.010” wire	0.014” max
Method of Supply	Sterile and single use	Sterile and single use	Same as Predicate Device and Reference Device

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance bench testing and animal testing (**Table 2**) indicate that ECLIPSE 2L (Subject Device) meets established performance requirements and is substantially equivalent for its intended use.

Table 2: Performance Bench Testing and Animal Testing Summary

Performance Bench Testing		
Tests	**Test Method Summary**	**Results**
Corrosion Resistance	The test article is immersed in sodium chloride solution before being placed in boiling distilled or deionized water. Subsequently, the test article is examined visually for evidence of corrosion.	All test samples met acceptance criteria.
Particulate Matter Characterization	Particulate matter in injections of the sterilized device were quantified after pre-conditioning per IFU and simulated use. Particulate matter characterization of the Subject Device was compared to the Predicate Device.	All test samples met acceptance criteria. Particulate matter characterization of the Subject Device was comparable to Predicate Device.
Coating Integrity and Adherence	Test samples were dyed and gone through simulated use testing. Inspect the coating quality of the dyed catheter under a microscope.	All test samples met acceptance criteria.
Compatibility and Coil Remodeling	The compatibility of 6F Guide catheter with microcatheter, balloon coiling and the use of stent was evaluated and rated. No coating particulate shall be observed during and post simulated use.	All test samples met acceptance criteria.
Simulated Use/Coating Lubricity and Durability	The clinical use of the device *in vitro* using a cerebrovascular benchtop model and the lubricity/durability of the coating was evaluated and rated. No coating particulate shall be observed during and post	All test samples met the acceptance criteria. The overall performance of the Subject Device is equivalent or better than the Predicate Device.

	simulated use. The overall performance was compared to the competitor devices.	
Flow Rate	The injection flow rate of saline and contrast media of the device is measured. The flow rate is measured for reference.	Testing was conducted for reference only.
Dynamic Burst	Catheter hub and shaft junctions shall not burst when injected with saline and contrast media under hydrostatic pressure by using an injection system.	All test samples met the acceptance criteria.
Liquid Leak	Devices were tested for liquid leakage. No liquid shall be leaking from hub and catheter shaft under pressure.	All test samples met the acceptance criteria.
Air Leak	Devices were tested for air leakage. Air bubbles shall not leak into the hub assembly during aspiration via syringe.	All test samples met the acceptance criteria.
Static Burst	Perform static burst testing per ISO 10555-1. The guidewire lumen shall not burst per specification.	All test samples met the acceptance criteria.
Torque Strength	Torque strength was determined by number of turns-to-failures. Torque strength of the Subject Device was compared to the Predicate Device.	All test samples met the acceptance criteria. The torque strength of the Subject Device is equivalent or better to the Predicate Device.
Physical Attributes	Inspect and measure dimensions for both the catheter and the balloon per product specification.	All test samples met the acceptance criteria.
Dead Space Volume	Determine the dead space volume for both the guidewire lumen and inflation lumen by using syringe and syringe pump.	Testing was conducted for reference only.
Balloon Deflation Time	Perform balloon deflation time testing by determining the time required to deflate the balloon from the rated burst volume.	All test samples met the acceptance criteria.

Balloon Compliance	Perform balloon compliance testing by measuring the balloon OD while inflating incrementally to the max rated inflation volume.	All test samples met the acceptance criteria.
Balloon Fatigue	Perform balloon fatigue testing by evaluating the integrity of the test sample after repeated inflation cycles. No leakage or rupture shall be observed after 20 cycles (inflation/deflation) to rated burst volume.	All test samples met the acceptance criteria.
Balloon Burst Volume	Determine the burst volume of the test samples by incrementally inflating the balloon with solution until burst failure.	All test samples met the acceptance criteria.
Kink Resistance	Perform kink resistance testing by wrapping the test point with an appropriate pin gauge to achieve a full 180º turn. Verify the OD has not changed and the catheter is not kinked using a microscope. Kink resistance of the Subject Device was compared to the Predicate Device.	All test samples met the acceptance criteria. The kink resistance performance of the Subject Device is equivalent or better to the Predicate Device.
Surface Contamination	Test samples were visually inspected for surface contamination under 2.5x magnification. The entire catheter surface should be free of presence of particulate.	All test samples met the acceptance criteria.
Tensile Force	Perform tensile force testing per ISO 10555-1. • Peak tensile strength of distal tip should be ≥ 3N (OD ≥.55mm <.75mm) • Peak tensile strength of catheter bonds should be ≥ 5N (OD ≥.75mm < 1.15mm)	All test samples met the acceptance criteria.
Gauge Test	• Perform gauge testing per ISO 594-1. Reference conical gauge and the inflation port opening should align in the limit planes. No rocking should be evident between the reference gauge and the fitting.	All test samples met the acceptance criteria.

	• Reference conical gauge and the guidewire port opening should align in the limit planes. No rocking should be evident between the reference gauge and the fitting.	
Ease of Assembly	Perform ease of assembly testing per ISO 594-2. • A satisfactory fit is achieved with the inflation port and reference fitting. • A satisfactory fit is achieved with the guidewire port and reference fitting.	All test samples met the acceptance criteria.
Unscrewing Torque	Perform unscrewing torque testing per ISO 594-2. • Inflation port shall remain attached to the reference fitting after applying an unscrewing torque of 0.02+0/-0.002 N•m for 10 seconds minimum. • Guidewire port shall remain attached to the reference fitting after applying an unscrewing torque of 0.02+0/-0.002N•m for 10 seconds minimum.	All test samples met the acceptance criteria.
Resistance to Overriding	Perform resistance to overriding testing per ISO 594-2. • The reference fitting shall not override the threads of the inflation port after applying a minimum torque of 0.15 N•m for 5 seconds. • The reference fitting shall not override the threads of the guidewire port after applying a minimum torque of 0.15 N•m for 5 seconds.	All test samples met the acceptance criteria.
Separation Force	Perform separation force testing per ISO 594-2. • Inflation port shall remain attached to the reference fitting after applying a max force of 35N for 10 seconds minimum.	All test samples met the acceptance criteria.

	• Guidewire port shall remain attached to the reference fitting after applying a max force of 35N max for 10 seconds minimum.	
Stress Cracking	Perform stress cracking testing per ISO 594-2. There shall be no evidence of stress cracks on the hub.	All test samples met the acceptance criteria.
Catheter Flexural Fatigue	The catheter flexural fatigue should be acceptable if the following tests passed: • Simulated Use • Dynamic Burst • Liquid Leakage • Air Leakage • Static Burst	All test samples met the acceptance criteria.
DMSO Compatibility	The device is DMSO Compatible if the following tests passed after DMSO Conditioning: • Simulated Use • Dynamic Burst • Liquid Leakage • Air Leakage • Static Burst • Balloon Deflation • Balloon Compliance • Balloon Fatigue • Balloon Burst • Tensile Strength	All test samples met the acceptance criteria.
Packaging Integrity Test		
Visual Inspection	Visually inspect packaging for any signs of damage. All seals shall be free of incomplete seals, voids, channels, wrinkles, foreign material in the seal and/or over heated sections. Labels shall be legible and intact, with no damage or delamination.	All test samples met the acceptance criteria.

Bubble Leak Test	Perform bubble leak test per ASTM F2096-11. All samples must exhibit no leaks.	All test samples met the acceptance criteria.
Seal Strength	Perform seal strength test per ASTM F88/F88M-15.	All test samples met the acceptance criteria.
Performance Animal Testing		
Animal Testing (GLP)	Animal testing is to evaluate the *in vivo* performance of the device in an acute porcine model. Trackability and handling of the catheter, radiopacity, and the balloon test occlusion were assessed. Subject device was compared to predicate devices.	All test samples met the acceptance criteria. Trackability and handling of the catheter, radiopacity, and the balloon test occlusion were comparable to predicate device.

Biocompatibility: Results of the biocompatibility testing (**Table 3**) indicate that ECLIPSE 2L (Subject Device) is biocompatible and is substantially equivalent for its intended use.

Table 3: Biocompatibility Test Summary

Test	Results	Conclusion
Cytotoxicity – Extraction **ISO 10993-5**	The test article extract showed no evidence of lysed cells or intracytoplasmic granules, with an average grade of 0 (no reactivity).	Non-cytotoxic
Sensitization - ISO Guinea Pig Maximization Sensitization Test-(2 Extracts) **ISO 10993-10**	The normal saline extract of the test material had a sensitization response of "0" under valid test condition. The sesame oil extract of the test material had a sensitization response of "0" under valid test condition. The test article did not elicit a sensitization response. The topical application of the sesame oil extract evaluated at a concentration of 100% did not induce delayed sensitization in the guinea pig (grade 0).	Did not elicit sensitization response

Irritation or Intracutaneous – ISO Intracutaneous Study in Rabbits – Two Extracts **ISO 10993-10**	The differences in the mean test and control scores of the extract dermal observations were 1.0 or less, indicating that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article	Non-irritant
Acute Systemic Toxicity – ISO Acute Systemic Toxicity Study in Mice – Two Extracts **ISO 10993-11**	The vehicle control treated animals had no signs of toxicity at any of the observation periods and no animals lost weight in excess of 10%, indicating a valid test. None of the test article treated animals were observed with clinical signs consistent with toxicity at any of the observation periods. Body weight changes were within acceptable parameters over the course of the study. These findings indicate that the requirements of the ISO Acute Systemic Injection Test have been met by the test article.	Non-toxic
Systemic Toxicity – ISO Materials Mediated Rabbit Pyrogen **ISO 10993-11**	During the 3-hour observation period, none of the rabbits administered with the test article extract had a temperature rise ≥ 0.5 °C at the required observation time points. This response did not exceed the USP limit and meets the requirements for this test. Therefore, these results indicate that the test article was determined to be non-pyrogenic.	Non-pyrogenic
Hemocompatibility-Hemolysis (Direct) **ISO 10993-4**	The difference between the hemolytic indexes of the test article and the negative control equals 0.00 percent. This result placed the test article in the non-hemolytic range.	Non-Hemolytic
Hemocompatibility – ASTM Hemolysis (Extract Method) **ISO 10993-4**	The difference between the hemolytic indexes of the test article and the negative control equals 0.00 percent. This result placed the test article in the non-hemolytic range.	Non-Hemolytic

Hemocompatibility – Complement Activation – SC5b-9 **ISO 10993-4**	The test article result reported there was statistically less activation than that of the predicate device.	Passed
Hemocompatibility – Partial Thromboplastin Time (PTT) **ISO 10993-4**	The test article and the predicate device were not statistically different. The clotting times exhibited by the test article were similar when compared to the clotting times exhibited by the predicate device. All the acceptance criteria were met.	Passed
Hemocompatibility – Platelet & Leukocyte Counts (PLC) **ISO 10993-4**	The platelet and leukocyte count of the test article were not statistically significant (one-way ANOVA, $p>0.05$) when compared to the comparison article. Therefore, the statistical analysis indicates that the test article is comparable to the comparison article.	Passed

Shelf life: The accelerated shelf life testing for ECLIPSE 2L has been conducted (T=1 years accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness are raised. Based on the results, we can conclude that ECLIPSE 2L will perform as intended to the Design Specification. ECLIPSE 2L will be labeled for 1-year shelf life.

Packaging: The packaging validation, T=1 year accelerated aging was performed on the ECLIPSE 2L. The results from packaging testing conducted on ECLIPSE 2L showed that the acceptance criteria were met. Therefore, we can conclude the ECLIPSE 2L packaging will provide the adequate and effective protection and sterile barrier requirements.

Sterilization: ECLIPSE 2L is sterilized using 100% Ethylene Oxide (EO) gas in the same manner as FDA cleared predicate device, Scepter C/XC Occlusion Balloon Catheter (K121785) and HyperGlide and HyperForm Occlusion Balloons (K101570). ECLIPSE 2L is sold sterile, for single use and single patient only. The sterilization validation was performed and documented. The sterilization validation results showed that the sterilization dose and routine sterilization process was validated to achieve a SAL of 10^{-6} for the ECLIPSE 2L.

Test Description	**Test Summary**	**Results**
Original Sterilization Validation and adoption	100% EO is used to sterilize the device to achieve a minimum SAL of 10^{-6}. The validation was conducted in accordance with ISO 11135. The original validation of the EO sterilization cycle of a worst-case device family was performed using one (1) fractional exposure cycle, three (3) half exposure cycles and one (1) full exposure cycle, overkill approach described in ISO 11135. The subject device was adopted to the original validated sterilization cycle by performing one (1) full cycle.	The validation study demonstrated that the sterilization process and equipment are capable of reliably and consistently sterilizing the devices to a minimum SAL of 10^{-6}. Fractional cycles, half cycles, and full cycles met the acceptance criteria. The subject device was successfully adopted to the original sterilization validation by performing one (1) full cycle.
EO and ECH Residuals	EO and ECH residuals were measured per ISO 10993-7: 2008.	The residual traces of EO and ECH for the subject device are below the limits specified in ISO 10993-7.
Bacterial Endotoxin Levels	LAL testing was conducted in accordance with FDA guidance document (June 2012), USP<85>, and European Pharmacopeia BET 2.6.14	< 2.15 EU/device

CONCLUSIONS

The ECLIPSE 2L met all specified criteria. We conclude that the Subject Device, ECLIPSE 2L, is substantially equivalent in its intended use, design, material, performance, and the underlying fundamental scientific technology used, to the Predicate Device, Scepter C/XC Occlusion Balloon Catheter and the Reference Device, HyperGlide and HyperForm Occlusion Balloons.