March 1, 2022

ArtVentive Medical Group, Inc.
Anil Bhalani
RA/QA Consultant
1797 Playa Vista
San Marcos, California 92708

Re: K212057
Trade/Device Name: Endoluminal Occlusion System, EOS-X, Endoluminal Occlusion System, EOS
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: January 26, 2022
Received: January 31, 2022

Dear Anil Bhalani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212057

Device Name

Endoluminal Occlusion System (EOS-X)

Indications for Use *(Describe)*

The ArtVentive Endoluminal Occlusion System - EOS-X is indicated for arterial and venous embolization in the peripheral vasculature.

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

ArtVentive Endoluminal Occlusion System (EOS-X)™

510(k) Number	**K212057**
Applicant:	ArtVentive Medical Group, Inc. 1797 Playa Vista San Marcos, CA 92708
Company Contact:	Anil Bhalani RA/QA Consultant Phone: 949-596-9001 Email: anilbhalani@artventivemedical.com
Date Summary Prepared:	June 25, 2021
Device Trade Name:	ArtVentive Endoluminal Occlusion System (EOS-X)™
Common/Classification Name:	Vascular embolization device, Class II
Regulation Number/Name:	21 CFR §870.3300 - Vascular embolization device
Review Panel:	Cardiovascular
Product Code:	KRD
Predicate Devices:	Endoluminal Occlusion System (EOS)™ (K150402)

Device Description:

The ArtVentive Endoluminal Occlusion System (EOS-X) has been developed for arterial and venous embolization in the peripheral vasculature. The system consists of three major components: a preloaded implant, the delivery catheter, and the guide catheter with dilator. The EOS-X is intended for single use only.

Like the predicate ArtVentive Endoluminal Occlusion System (EOS)™, the ArtVentive Endoluminal Occlusion System (EOS-X) is comprised of an implant made of a Nitinol coil scaffold with an ePTFE occlusion membrane and is designed with radial force sufficient to provide stiffness and strength against the vessel wall and minimize post-deployment migration. The delivery system is made up of a delivery catheter and the guide catheter with dilator. The implant delivery catheter contains one implant loaded on the distal end and a deployment handle on the proximal end connected by the shaft. The delivery catheter has a low profile and is flexible to allow for trackability and pushability. The implant itself and the catheter's distal end are visible under fluoroscopy.

The guide catheter is a braided shaft with a stiff proximal section and a more flexible distal section to enable tracking through tortuous peripheral vasculature. A radiopaque marker on the distal end of the catheter is visible under fluoroscopy. The tip of the guide catheter is tapered to fit over the dilator. The dilator fits inside the guide catheter exiting out through the distal end. The dilator also has a tapered end for ease of advancement into the blood vessel. The guidewire and dilator are removed from the guide catheter once it is in position for delivery of the implant.

Comparison to Predicate Device:

Manufacturer/ Device	**ArtVentive Endoluminal Occlusion System (EOS-X)**	**ArtVentive Endoluminal Occlusion System (EOS)**
510(k) Number	K212057	K150402
Application / Product Code	21 CFR 870.3300 (KRD)	21 CFR 870.3300 (KRD)
FDA Classification	Class II	Class II
Technological Characteristics		
Intended Use	The ArtVentive Endoluminal Occlusion System (EOS-X)™ is intended for arterial and venous embolization in the peripheral vasculature.	The ArtVentive Endoluminal Occlusion System (EOS)™ is intended for arterial and venous embolization in the peripheral vasculature.
Design Features	Flexible, low profile device for immediate, acute occlusion of the target vessel. The device incorporates an ePTFE cover. Retrievable; may be removed during deployment and re-positioned. Two-stage deployment handle on the proximal end. The catheter has a stiff proximal section for pushability and a flexible distal section for trackability. The deployment handle has a side port to accommodate syringe attachment to flush the catheter of air and to pre-expand the ePTFE membrane before deploying the implant.	Flexible, low profile device for immediate, acute occlusion of the target vessel. The device incorporates an ePTFE cover. Retrievable; may be removed during deployment and re-positioned. Two-stage deployment handle on the proximal end. The catheter has a stiff proximal section for pushability and a flexible distal section for trackability. The deployment handle has a side port to accommodate syringe attachment to flush the catheter of air and to pre-expand the ePTFE membrane before deploying the implant.
Implant Material	Nitinol coil with an ePTFE polymeric cover	Nitinol coil with an ePTFE polymeric cover
Detachment	Mechanical in nature	Mechanical in nature
Implant Size	5mm, 8mm, 11mm, 16mm	5mm, 8mm, 11mm
Treatment Method	Permanent Implant	Permanent Implant
How Applied	Via delivery catheter through a guide catheter to target vessel	Via delivery catheter through a guide catheter to target vessel

Implant and Guide Catheter Selection Matrix:

Implant Size	EOS or EOS-X	Reference Vessel Diameter	Reference ArtVentive Guide Catheter Compatibility
5mm	EOS-X	2.0mm - 5mm	4F or larger
8mm	EOS-X	4.5mm - 8mm	5F or larger
11mm	EOS-X	7.5mm - 11mm	6F or larger
16mm	EOS-X	10.5mm - 16mm	6F or larger
5mm	EOS	3.0 mm – 5.0mm	6F or larger
8mm	EOS	4.5mm - 8mm	6F or larger
11mm	EOS	7.5mm - 11mm	7.5F or larger

Indications for Use:
The ArtVentive Endoluminal Occlusion System (EOS-X) is indicated for arterial and venous embolization in the peripheral vasculature.

Contraindications:
• Implantation in proximity to high motility (locomotor) muscles

Intended Use:
The ArtVentive Endoluminal Occlusion System (EOS-X) has been developed for arterial and venous embolization in the peripheral vasculature. The device is provided sterile and is intended for a single use only. It is intended to be placed in the peripheral vasculature using a guide catheter of appropriate size.

Technological Characteristics:
The Fundamental Scientific Technology of the previously cleared predicate device, The ArtVentive Endoluminal Occlusion System (EOS) via K992189 is substantially equivalent to The ArtVentive Endoluminal Occlusion System (EOS-X).

Performance Data Summary:
Engineering Performance Studies conducted demonstrated that the ArtVentive Endoluminal Occlusion System (EOS-X) which adds a larger16mm size of delivery catheter/implant for use with the 6F size guide catheter as well as the minor design modifications made to the 5mm and 8mm and 11mm sizes as compared to its predicate performed as intended. The following testing was repeated for the additional sizes of the device: dimensional and functional design verification/validation, MRI compatibility, corrosion, and radial strength. The design verification and validation testing were also repeated as necessary for the design modifications to the previously cleared 5mm and 8mm delivery catheter/implant and the 6 Fr guide catheter. The review of the technological characteristics, indications for use, and verification and validation information provided in the 510(k) Premarket Notification demonstrates that the ArtVentive Medical Group Endoluminal Occlusion System-EOS-X is substantially equivalent to its predicate device.

Substantial Equivalence:
The ArtVentive Endoluminal Occlusion System (EOS-X) is substantially equivalent to its predicate device, the ArtVentive Endoluminal Occlusion System (EOS) and introduces no new safety and effectiveness issues when used as instructed by accompanying labels and labelling.

The substantial equivalence is based on the information provided in this 510(k) Premarket Notification which demonstrates that the EOS-X and EOS have equivalent technological characteristics, mechanism of action, intended use and physical characteristics. The design modifications made to the EOS-X device in sizes 5mm, 8mm and 11mm delivery catheter/ implant and associated guide catheters are also substantially equivalent to the predicate device when used according to its intended use. The larger size 16mm delivery catheter/implant is also similar to the other smaller models of EOS and EOS-X in technological characteristics, mechanism of action, intended use and physical characteristics. The equivalence is based on repeating the applicable design verification and validation testing.

Conclusion:
Information in this 510(k) submission demonstrates that the ArtVentive Endoluminal Occlusion System (EOS-X) is substantially equivalent to its predicate device.