March 21, 2022

Artio Medical, Inc.
Erdie Peralta
Vice-President, Clinical And Regulatory Affairs
127 Independence Drive
Menlo Park, California 94025

Re: K213200
Trade/Device Name: Solus Gold Embolization Device
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: February 14, 2022
Received: February 15, 2022

Dear Erdie Peralta:

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, PhD
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)*
K213200

Device Name
Solus Gold Embolization Device

Indications for Use *(Describe)*
The Solus Gold Embolization Device is indicated to obstruct or reduce the rate of blood flow 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

510(k) Number: **K213200**

I. SUBMITTER INFORMATION

Submitter: Artio Medical, Inc.
127 Independence Drive
Menlo Park, CA 94025

Contact: Erdie DePeralta
Vice President, Clinical and Regulatory Affairs
Phone: (978) 408-0949
Email: edeperalta@artiomedical.com

Date Summary Prepared: March 18, 2021

II. SUBJECT DEVICE INFORMATION

Device Trade Name: Solus Gold™ Embolization Device
Common Name: Device, Vascular, For Promoting Embolization
Classification Name: Vascular Embolization Device
Regulation Number: 21 CFR §870.3300
Regulatory Class: II
Product Code: KRD
Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION:

Predicate Device: Reverse Medical Micro Vascular Plug System (K141313)

IV. DEVICE DESCRIPTION:

The Solus Gold Embolization Device is a vascular plug device intended to obstruct or reduce the rate of blood flow in the peripheral vasculature. It is comprised of an implant assembly and a delivery system assembly. The delivery system assembly is comprised of a microcatheter and a delivery catheter. A rotating hemostatic valve (RHV) and a 3-way stopcock is provided on the hub of the delivery catheter for injecting fluid to facilitate expansion of the implant. The Solus Gold implant is available in 3 mm – 6 mm diameters. All implant sizes are provided with the same delivery system, and the physician selects the device size based on the treatment plan. The Solus Gold implant assembly consists of a gold implant body, a distal neck subassembly, and an implant mating component. The proximal end of the implant is joined to the delivery catheter through the implant mating component, which is a platinum tubular segment secured to the inside of the proximal neck of the gold implant body with adhesive. The distal neck subassembly is comprised of two stacked silicone valves and a platinum (Pt) marker band that are contained within a stainless-steel housing and bonded to the distal neck of the implant with adhesive. The distal neck subassembly of the implant is mounted to the microcatheter over a preparation tool, which is removed by the user after device preparation. The implant is pleated and folded, loaded onto the delivery catheter and microcatheter, and protected with a sheath. The device is provided sterile and is intended for single use only.

V. INDICATIONS FOR USE

The Solus Gold Embolization Device is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.

VI. COMPARISON OF INTENDED USE, INDICATIONS FOR USE, AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	Subject Device Solus Gold™ Embolization Device	Predicate Device Reverse Medical Micro Vascular Plug System (K141313, K150108)
Product Code	KRD	Same as subject device
Regulation No.	21 CFR §870.3300	Same as subject device
Regulation Name	Vascular embolization device	Same as subject device
Intended Use	To obstruct or reduce the rate of blood flow in the peripheral vasculature	Same as subject device
Indications for Use	The Solus Gold Embolization Device is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.	The Reverse Medical Micro Vascular Plug System is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.
Anatomical Site	Peripheral vasculature	Same as subject device
Target Vessel Diameter	1.5 – 5.0 mm	1.5 – 7.0 mm
Implant Diameter x Implant Length (Expanded or Unconstrained)	3 mm x 6.7 mm, 3.5 mm x 7.6 mm, 4 mm x 8.4 mm, 4.5 mm x 9.3 mm, 5 mm x 10.2 mm, 5.5 mm x 11.1 mm, 6 mm x 11.9 mm	MVP-3: 5.3 mm x 12 mm MVP-5: 6.5 mm x 12 mm MVP-7: 9.2 mm x 16 mm
Implant Materials	Gold, platinum/iridium, stainless steel, silicone, adhesive	Nitinol, platinum, ePTFE
Delivery System Materials of Construction	PTFE, PEBA, polyurethane, nylon, nitinol, stainless-steel, platinum/iridium, liquid crystal polymer (LCP), adhesive, polyolefin, hydrophilic coating	Stainless steel, solder, polypropylene, urethane, cyanoacrylate
Implant Description	Ovoid gold implant body with proximal neck implant mating component and distal neck subassembly, expanded by injection of saline or a mixture of saline and contrast	Ovoid nitinol frame with an ePTFE cover over the proximal portion, self-expanding
Implant Radiopacity	Entire gold implant body and proximal and distal platinum/iridium marker bands	Proximal and distal marker bands only
Delivery method	Implant comes attached to the delivery catheter and microcatheter, is delivered over a .014" guidewire to the intended treatment site, expanded, and detached from the delivery catheter and microcatheter.	Implant comes attached to a delivery wire, is pushed through a commercially available catheter to the intended treatment site, expanded, and detached from delivery wire.
Catheter Compatibility	Compatible with commercially available catheters: All implant sizes: ≥ 0.070" ID catheter (6 Fr)	Compatible with commercially available catheters: MVP-3Q: 0.021" - 0.027" ID catheter MVP-5Q: 0.027" ID catheter MVP-7Q: 0.041" ID catheter
Microcatheter Maximum Length	154 cm	150 cm
Delivery System Maximum Length	Delivery catheter length: 136 cm	Delivery wire length: 160 – 180 cm
How Transferred to Catheter	Attached to delivery system, inserted into vasculature over a guidewire and through a compatible commercially available catheter	Attached to delivery wire, inserted into vasculature through a compatible, commercially available catheter

Attribute	Subject Device Solus Gold™ Embolization Device	Predicate Device Reverse Medical Micro Vascular Plug System (K141313, K150108)
Detachment	Mechanical	Same as subject device
How Provided	Sterile, single-use	Same as subject device
Sterilization Method	Ethylene oxide	Same as subject device

VII. PERFORMANCE DATA

Sterilization Validation:

Sterilization conditions were validated according to ANSI / AAMI /ISO 11135, Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Packaging & Shelf-Life Validation:

Packaging Validation for the Solus Gold Embolization Device included: Pouch Seal Strength, Packaging Integrity, Unique Device Identification Barcode Quality, and Microbial Barrier testing was conducted at both the T=0 timepoint and the accelerated aging timepoint at T=6 months. Product Integrity Following Transit and Device Condition after Transit was done at T=0. Additionally, the performance testing results of the accelerated aged samples demonstrated that the device performs as intended throughout its labeled shelf-life.

Biocompatibility:

The biological evaluation for the Solus Gold Embolization Device was conducted in accordance with the FDA recognized consensus standard (ANSI/AAMI/ISO 10993-1) "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process" and FDA's applicable guidance document, "Use of International Standard ISO 10993" issued September 2020. The implant of the Solus Gold Embolization Device is categorized as "Long Term Contact with Circulating Blood." The non-implantable delivery system, including the microcatheter and delivery catheter, is categorized as "Externally Communicating Device in Limited Contact with Blood." Pursuant to ISO 10993-1 and the 2020 FDA Guidance, biological risks were addressed by: appropriate testing, a chemical characterization assessment, a literature review or a combination of these approaches.

Bench Performance Testing:

Pursuant to the Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices (issued December 29, 2004), bench testing of the Solus Gold Embolization Device was performed. Bench testing of the Solus Gold Embolization implant included: 1) implant compression; 2) implant tensile; 3) implant expansion; 4) implant maximum pressure; 5) distal neck sub-assembly flow; 6) implant dimensions; 7) corrosion resistance; and 8) MR compatibility. Delivery catheter and microcatheter verification testing included: 1) microcatheter distal flexibility; 2) microcatheter liquid leak under pressure and delivery catheter liquid leak and burst; 3) catheter air leak under vacuum; 4) catheter kink resistance; 5) catheter torque durability; 6) catheter tensile force; 7) inadvertent implant detachment; 8) catheter dimensions; 9) luer hub compatibility; 10) coating integrity; and 11) catheter corrosion resistance. Additionally, verification testing of the complete Solus Gold Embolization Device included: 1) simulated use testing; 2) microcatheter retraction tensile force; 3) implant detachment tensile force; and 4) particulate. These bench performance studies confirm that the device performed as intended per the

product specifications and also demonstrated that the Solus Gold Embolization Device is substantially equivalent to the MVP predicate device.

Human Factors Assessment:

The Solus Gold Embolization Device was evaluated by fifteen (15) intended users in a simulated clinical setting. This testing was conducted pursuant to the applicable requirements of FDA's Guidance Document titled "Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016)." For this evaluation, the users were trained by Artio personnel. After a decay period of at least 1 hour post training, users were provided with a Solus Gold Embolization Device and the proposed instructions for use. Critical tasks were assessed through observation during simulated use and through user knowledge assessments about the device's labeling and procedure steps that were not amendable to simulated use testing. Additionally, the test subjects completed a survey. The human factors assessment demonstrated that the device labeling and training provided to the intended users allowed for the proper use of the Solus Gold Embolization Device in its intended use environment. Further, this assessment confirmed that all identified risks were considered acceptable and that no new risks were identified.

Pre-Clinical Animal Performance Testing

The Solus Gold Embolization Device and the MVP predicate device were evaluated in a chronic 90-day canine animal study model. Specifically, safety, effectiveness, *in vivo* performance and handling evaluations were conducted to assess device performance in accordance with the design requirements and product specification. Additionally, *in vivo* thrombosis testing (thrombogenicity) was conducted as part of the GLP animal study. The study was conducted under Good Laboratory Practice (GLP) controls pursuant to 21 CFR §58. The study complied with the requirements of Vascular and Neurovascular Embolization Devices - Class II Special Controls Guidance Document for Industry and FDA Staff (Dec. 2004), EN ISO 10993-4:2017 Biological Evaluation of Medical Devices Part 4: Selection of Test for Interactions with Blood and FDA General Considerations for Animal Studies for Cardiovascular Devices – Guidance for Industry and FDA Staff (July 2010). A total of seven (7) canine underwent treatment procedures with the Solus Gold Embolization Device and/or the MVP predicate device (Day 0). One Solus Gold Embolization Device (2.5 mm to 6.0 mm with 0.5 mm increments) or the MVP predicate device (MVP-3Q, MVP-5Q, MVP-7Q devices) was placed per treated artery (internal thoracic artery, renal artery, external iliac artery, and splenic artery. Follow-up angiography occurred on Day 28 ± 3 days after the treatment procedure. Terminal procedures took place on Day 90 ± 7 days. Acute embolization effectiveness was assessed by the time to achieve complete (Grade 0 or Grade 1) target vessel segment occlusion by angiography on Day 0. Chronic embolization effectiveness (durability) was assessed by target vessel segment occlusion by angiography (Grade 0 – 4) and morphometric percent vessel lumen occlusion by histology on Day 90.

The mean time to achieve complete (Grade 0 or Grade 1) target vessel segment occlusion by angiography on Day 0 was .50 minute for the Solus Gold Embolization Device and 1.94 minutes for the MVP predicate device. Complete (Grade 0 or Grade 1) target vessel segment occlusion was observed at 90 days were 14/14 for the Solus Gold Embolization Device and 2/14 for the MVP predicate device. Mean (maximal) percent vessel lumen occlusion by histology at 90 days was 100% for the Solus Gold Embolization Device and 79.6 % for the MVP predicate device. No complications were observed for either the Solus Gold Embolization Device or the MVP predicate device.

VIII. CONCLUSION

Information in this 510(k) submission demonstrate that the Solus Gold Embolization Device is substantially equivalent to the MVP predicate device. Substantial equivalence is based on comparative bench and animal testing, a comparison of the component materials and comparison of the technological characteristics of the Solus Gold Embolization Device and the MVP predicate device. The Solus Gold Embolization Device is substantially equivalent in its intended use, indications for use, and performance to the MVP predicate device. The differences between the Solus Gold Embolization Device and the MVP predicate device do not raise any new or different questions related to the device safety or effectiveness. Therefore, the Solus Gold Embolization Device is substantially equivalent to the MVP predicate device.