



February 4, 2020

ClearStream Technologies Ltd.
Melanie Hadlock
Regulatory Affairs Specialist II
Moyné Upper
Enniscorthy, Co. Wexford, Ireland

Re: K191532

Trade/Device Name: Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device

Regulation Number: 21 CFR 870.3300

Regulation Name: Vascular Embolization Device

Regulatory Class: Class II

Product Code: KRD

Dated: December 30, 2019

Received: December 31, 2019

Dear Melanie Hadlock:

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,

For

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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K191532

Device Name
Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices

Indications for Use (Describe)

The Caterpillar and Caterpillar Micro Arterial Embolization Devices are indicated for arterial embolization in the peripheral vasculature. The Caterpillar and Caterpillar Micro Arterial Embolization Devices are contraindicated for use in vessels subject to cyclic bending, such as highly locomotive joints or muscle beds.

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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Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device
510(k) Summary

21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

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480.894.9515
Fax: 480.966-7062
Contact Person: Melanie Hadlock, Senior Regulatory Specialist

Date of Submission: June 7, 2019

Subject Device:

Device Trade Name:	Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device
Common or Usual Name:	Device, Vascular, for Promoting Embolization
Classification:	Class II
Classification Name:	Vascular Embolization Device, KRD
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.3300

Predicate Device:

Device Trade Name:	Amplatzer™ Vascular Plug II (AVP II)
Common or Usual Name:	Device, Vascular, for Promoting Embolization
Classification:	Class II
Classification Name:	Vascular Embolization Device, KRD
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.3300
510(k) Numbers:	K071699, cleared August 15, 2007

Reference Device:

Device Trade Name:	Amplatzer™ Vascular Plug 4 (AVP4)
Common or Usual Name:	Device, Vascular, for Promoting Embolization
Classification:	Class II
Classification Name:	Vascular Embolization Device, KRD
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.3300
510(k) Number:	K113658, cleared June 12, 2012

Device Description:

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are self-expanding arterial occlusion plugs. The devices consist of the following components and are intended to be a permanent implant: cobalt-chrome stem, nickel-titanium fibers, platinum-iridium radiopaque marker bands, and a polyurethane and polyethylene occlusion membrane.

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device Systems are packaged as a single unit with the implant, loader, dispenser hoop, detachable delivery wire, and torque tool. The Caterpillar™ Micro delivery wire is coated with a hydrophilic coating. While the Caterpillar™ delivery wire has a PTFE hydrophobic coating. The system is provided sterile and non-pyrogenic and is intended for single use only.

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device is designed for a specific arterial diameter range. The artery diameter range and required delivery catheter size (inner diameter (ID)) for deployment are provided in the table below.

Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device Product Characteristics

Product Name	Product Reference	Target Artery Diameter (mm)	Delivery Catheter Compatibility: Inner Diameter (in/mm)	Marker to Marker Length (mm) ¹	Maximum Deployed Length (mm) ²	Delivery Wire Length (cm)
Caterpillar™ Micro	027	1.5 - 4	0.027 / 0.686	7	16	170
Caterpillar™	038	3 - 6	0.038 / 0.965	17	26	155
	056	5 - 7	0.056 / 1.422	18	37	155

1. The Marker to Marker Length is the distance between the most distal radiopaque marker band to the most proximal radiopaque marker band.
2. The Maximum Deployed Length is the length from the distal fiber tips to the proximal fibers in the minimum target artery diameter.

Indications for Use:

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Devices are indicated for arterial embolization in the peripheral vasculature. The devices are contraindicated for use in vessels subject to cyclic bending, such as locomotive joints or muscle beds.

Comparison to Predicate device:

The Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device have the following similarities to the predicate device, the Amplatzer™ Vascular Plug II, AVP II (K071699, cleared August 15, 2007):

- Same intended use
- Similar target population
- Similar technological characteristics
- Similar user interface
- Same mechanism of action
- Same sterility assurance level and method of sterilization
- Similar materials

The reference device Amplatzer™ Vascular Plug 4, AVP4 (K113658, cleared June 12, 2012) has the above similarities and was used to support the methods used for characterization of delivery system performance based on similarities of the delivery system.

The subject devices, the Caterpillar™ and Caterpillar™ Micro Arterial Embolization Device, have the following changes:

- Contraindication
- A new implant design
- A modified delivery system

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate devices, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices, consensus standards, and internal risk assessment procedures, the following tests were performed on the subject device:

- Dimension
 - Implant Length
 - Catheter Compatibility
 - Delivery Wire Length and Outer Diameter
- Radial Force
- Luer Connection Testing
- Radiopacity
- Simulated Use
 - Visual Inspection
 - Delivery, Load, Track and Deployment Forces
 - Accuracy of Deployment
 - Detachment Time and Detachment Mechanism Reliability
 - Tensile and Torsional Strength
 - Recapture and Resheathing for Removal
- Delivery System Removal (withdrawal)
- Fatigue Resistance
 - Pulsatile and Pinching Compression
- Material Safety Testing
 - Corrosion Resistance

- Nickel Leaching
 - Particulate
- MRI Compatibility and Safety
- Packaging Testing
- Biocompatibility per ISO 10993
 - Cytotoxicity, sensitization (guinea pig maximization test), intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, genotoxicity (in vitro bacterial reverse mutation assay and in vitro mouse lymphoma assay), hemolysis (direct and indirect), and complement activation.
 - Biocompatibility endpoints for subchronic toxicity, implantation, chronic toxicity, and in vivo thrombogenicity were addressed within the chronic ovine animal study.
 - Biocompatibility endpoints for genotoxicity, chronic toxicity, and carcinogenicity were evaluated with chemical characterization testing and toxicological assessment

Pre-Clinical Animal Study:

A chronic ovine study was performed to evaluate the chronic safety and performance of the Caterpillar and Caterpillar Micro Arterial Embolization Devices. The animal study included evaluations for migration resistance, ease of delivery, occlusion efficiency, recanalization, deliverability, hemostasis after procedure, thrombogenicity, device safety, and freedom from complications for the duration of the study. The results demonstrated that the study device performance was equivalent or superior to control devices across each of the evaluated endpoints.

Conclusions:

The subject devices, the CaterpillarTM and CaterpillarTM Micro Arterial Embolization Device, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The CaterpillarTM and CaterpillarTM Micro Arterial Embolization Device are substantially equivalent to the legally marketed predicate device, the AmplatzerTM Vascular Plug II, AVP II (K071699, cleared August 15, 2007) and the reference device AmplatzerTM Vascular Plug 4, AVP 4 (K113658, cleared June 12, 2012).