April 25, 2020

Arch Catheter, LLC
% Mary Vater
510(k) Consultant
Medical Device Academy
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K192786
Trade/Device Name: Gatekeeper Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: September 27, 2019
Received: September 30, 2019

Dear Mary Vater:

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 Carmen Gacchina Johnson
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192786

Device Name
Gatekeeper Balloon Catheter

Indications for Use *(Describe)*
The Gatekeeper Balloon Catheter is indicated for temporary occlusion of vessels 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
K192786

I. SUBMITTER

Arch Catheter, LLC
621 Grand Harbor Boulevard
Ninety Six, SC, 29666 USA
Tel: 1.864.680.2568
Fax: 1.864.725.7910

Contact Person: Michael Zhadkevich, MD, PhD
Date Prepared: Sept. 27, 2019

II. DEVICE

Name of Device: Gatekeeper Balloon Catheter
Common Name: Occlusion balloon catheter
Classification Name: Vascular Clamp
Regulation: 21 CFR § 870.4450
Regulatory Class: Class II
Product Classification Code: MJN

III. PREDICATE DEVICE

Primary Predicate Manufacturer: CoAxia, Inc.
Primary Predicate Trade Name: FloControl Catheter
Primary Predicate 510(k): K090970

Secondary Predicate Manufacturer: Via Biomedical, Inc.
Secondary Predicate Trade Name: Stent Graft Balloon Catheter
Secondary Predicate 510(k): K091624

Secondary Predicate Manufacturer: QXMedical, LLC
Secondary Predicate Trade Name: Q50 PLUS Stent Graft Balloon Catheter
Secondary Predicate 510(k): K120381

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Gatekeeper Balloon Catheter is an over the wire (OTW) triple-lumen catheter with 2 compliant proximal and distal polyurethane balloons having a maximum diameter of 15 mm and 10 mm respectively. The 2 balloon lumens are connected to extension lines with stopcocks and are used to inflate and deflate the proximal and distal balloons. The third lumen is a guidewire lumen. The distance between the proximal and distal balloons is 2 cm. Two (2) radiopaque marker bands are located within the balloons at each end (30mm apart at the proximal balloon and 15mm apart at the distal balloon) to facilitate balloon placement prior to inflation. The catheter can accommodate a 0.014” diameter (or smaller) guidewire and is compatible with 6Fr (or larger) introducer sheath. The device is a single use, sterile device.

V. INDICATIONS FOR USE

The Gatekeeper Balloon Catheter is indicated for temporary occlusion of vessels in the peripheral vasculature.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

Compared to the predicate devices of the CoAxia FloControl Catheter (K090970), Via Biomedical Stent Graft Balloon Catheter (K091624), and QXMEDICAL Q50 PLUS Stent Graft Balloon Catheter (K120381), the subject Gatekeeper Balloon Catheter has the same intended use and mechanism of action for temporary occlusion of vessels. The indication statements for the predicate devices describe additional functions for expanding vascular prostheses, controlling blood flow, or occlusion of large vessels; but all devices are intended for temporary occlusion of vessels. The subject device has different technological characteristics of catheter design and materials that do not raise different questions of safety and effectiveness and were evaluated with non-clinical testing.

The subject device is designed to fulfill the requirements of the following recognized standards:

- 6-301 ISO 10555-1 Second edition 2013-06-15 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements
- 6-322 ISO 10555-4 Second edition 2013-06-15 Intravascular catheters -- Sterile and single-use catheters -- Part 4: Balloon dilatation catheters
- 6-408 ISO 10555-1 Second edition 2013-06-15 Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements [Including AMENDMENT 1 (2017)]

The following benchtop performance tests were conducted to demonstrate that the Gatekeeper Balloon Catheter performance complies with the standards.

- Visual Inspection
- Dimensional Inspection
- Freedom from Leakage
- Luer Syringe Compatibility
- Guidewire Compatibility
- Introducer Sheath Compatibility
- Balloon Compliance (Volume v. Diameter)
- Inflation Time
- Balloon Inflation Characteristics
- Radiopacity
- Shipping/ Distribution Testing
- Vessel Occlusion
- Balloon Fatigue
- Burst or Leak Volume
- Freedom from Fragmentation
- Tensile Strength (Hub to Shaft)
- Tensile Strength (Tip to Shaft)
- Tensile Strength (Extension Tube)
- Shelf Life Testing
- Package Integrity
- Environmental Conditioning
- Kink Testing
- Torque Testing
- Simulated Use

Biocompatibility testing was conducted in accordance with ISO 10993-1.

VII. CONCLUSIONS

The Gatekeeper Balloon Catheter has the same intended use as the predicate devices. The technological differences do not raise different questions of safety and effectiveness. Based on the results of non-clinical testing, the data supports the Gatekeeper Balloon Catheter is substantially equivalent to the predicate devices.