DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 27, 2017

Callisyn Biomedical, Inc.
% Gordon MacFarlane
Regulatory Project Manager
Icon
62 Forest Street, Suite 300
Marlborough, Massachusetts 01752

Re: K161967
Trade/Device Name: FluidiTube 2.7F Infusion Micro Catheter, 110 cm and 130 cm
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: December 28, 2016
Received: December 29, 2016

Dear Gordon MacFarlane:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161967

Device Name

FluidiTube® 2.7F Infusion Micro Catheter

Indications for Use *(Describe)*

The FluidiTube® 2.7F Infusion Micro Catheter is intended to facilitate infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, visceral vessels and all coronary vessels. It is also intended for drug infusion in intra-arterial therapy and embolic materials for hemostasis. The FluidiTube® 2.7F Infusion Micro Catheter is not to be used in cerebral blood vessels.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

5. 510(K) SUMMARY

510(k) Summary
for the Callisyn FluidiTube 2.7F Infusion Micro Catheter

(per 21CFR 807.92 and *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm*)

1. SUBMITTER/510(K) HOLDER

Callisyn Biomedical, Inc.
260 Candlestick Road
North Andover, MA 01845

Contact:	Shallwei Sun, General Manager
Contact's Phone:	+1 (978)-687-0596
Contact's Email:	Shallwei0@yahoo.com
Date Prepared:	July 14, 2016

2. DEVICE NAME

Trade Name:	Callisyn FluidiTube® 2.7F Infusion Micro Catheter
Classification Name:	Continuous flush catheter
Classification Panel:	Cardiovascular
Classification Regulation:	21 CFR 870.1210
Product Code:	KRA
Class:	II

3. PREDICATE DEVICE

- Progreat®, manufactured by Terumo Medical Corporation, K033913

4. DEVICE DESCRIPTION

The FluidiTube® 2.7F Infusion Micro Catheter is a tapered 2.7F/2.9F single lumen catheter with a luer lock hub designed to facilitate the access of distal vasculature over a guidewire. The FluidiTube® has a semi-rigid proximal shaft that becomes progressively more flexible towards the distal end. The shaft is reinforced with braided stainless steel wire for kink resistance. The inner lumen is lined with a lubricious material to facilitate the movement of a guidewire. The outer surface of the catheter has a hydrophilic coating that becomes lubricious when wet with saline or blood. The FluidiTube® catheter is introduced to the target location through a guiding catheter 0.038" (0.97 mm) or larger and is compatible with 0.021" (0.53 mm) guidewires or smaller.

Device configurations consist of one profile size (2.7F) with two different usable lengths (110cm, 130cm). The final device is packaged in a Tyvek pouch and sterilized by ethylene oxide (EO). The device is for single use only.

5. INDICATION FOR USE/INTENDED USE

The FluidiTube® 2.7F Infusion Micro Catheter is intended to facilitate infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, visceral vessels and all coronary vessels. It is also intended for drug infusion in intra-arterial therapy and embolic materials for hemostasis.

The FluidiTube® 2.7F Infusion Micro Catheter is not to be used in cerebral blood vessels.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

A summary comparison of technological characteristics, including design and materials is provided in the table below:

Feature	FluidiTube® 2.7F Infusion Micro Catheter (Callisyn Biomedical, Inc.)	Progreat® (Terumo Medical Corporation)
Regulatory Status	Subject Device	K033913
Indications for Use	The FluidiTube® 2.7F Infusion Micro Catheter is intended to facilitate infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, visceral vessels and all coronary vessels. It is also intended for drug infusion in intra-arterial therapy and embolic materials for hemostasis. The FluidiTube® 2.7F Infusion Micro Catheter is not to be used in cerebral blood vessels.	The Progreat® is intended for the infusion of contrast media into all peripheral vessels up to and including the cervical vessels, all vessels in the lower and upper extremities, visceral vessels, and all coronary vessels. The Progreat is also intended for drug infusion in intra-arterial therapy and the infusion of embolic materials for hemostasis in procedures including but not limited to Uterine Fibroid Embolization. The Progreat should not be used in cerebral vessels.
Hydrophilic Coating	Yes	Yes
Working Length	110cm and 130cm	100 – 150cm
Radiopaque Marker	Yes	Yes
Dimensions	Outer diameter distal: 2.7F, 0.90mm Outer diameter proximal: 2.9F, 0.97mm Inner diameter: 0.025in, 0.65mm	Outer diameter distal: 2.7F, 0.90mm Outer diameter proximal: 2.9F, 0.97mm Inner diameter: 0.025in, 0.65mm
Strain Relief and Hub	Yes	Yes
Guidewire Compatibility	0.021” (0.53mm) or smaller	0.021” (0.53mm) or smaller
Guiding Catheter Compatibility	0.038” (0.97mm) or bigger	0.038” (0.97mm) or bigger
Sterile	Yes (Ethylene Oxide)	Yes (Ethylene Oxide)
Single Use	Yes	Yes

The FluidiTube® 2.7F Infusion Micro Catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the Progreat Catheter K033913. Differences between the devices do not raise any significant issues of safety or effectiveness.

7. SUMMARY OF NON-CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Non-clinical testing of the Callisyn FluidiTube® 2.7F Infusion Micro Catheter to demonstrate that the device met its specifications is summarized below.

Biocompatibility Evaluation

Biocompatibility testing is summarized in the table below. Testing was conducted according to the referenced methodology.

Biocompatibility Evaluation and Extractables Testing	
Test	**Methodology**
Cytotoxicity	ISO 10993-5:2009
Irritation	ISO 10993-10:2010
Sensitization	ISO 10993-10:2010
Acute Systematic Injection	ISO 10993-11:2006
Materials Mediated Rabbit Pyrogen	USP <151>
Thrombosis (*in vivo*)	ISO 10993-4:2002
Hemolysis	ASTM F756-08
Complement Activation – C3a and SC5b-9 Assay	ISO 10993-4:2002
In vitro Mouse Lymphoma with Extended Treatment	ISO 10993-3:2003
In vivo Mouse Micronucleus Assay	ISO 10993-3:2003
ISO Bacterial Mutagenicity Test – Ames Assay	ISO 10993-3:2002
Extractables	ISO 10993-18:2005

Physicial and Mechanical Testing

Physical and mechanical testing is summarized below.

Physical and Mechanical Testing	
• Kink resistance	• Static Pressure (Burst)
• Tensile (Catheter)	• Trackability
• Tensile (Hub-catheter)	• Flow Rate
• Reliability (Marker Band Durability)	• Size, OD and ID
• Coating Lubricity	• Hydrophillic Coating Coverage
• Corrosion Resistance	• Paticulate Testing
• Torqueability Testing	• Liquid and Air Leakage Testing
• Guidewire Compatibility	• Guide Catheter Compatibility

In addition to the testing described above, the Callisyn FluidiTube® 2.7F Infusion Micro Catheter was also subject to shelf-life testing, packaging validation as per ISO 11607-1:2006, and simulated transport testing as per ISTA 2A:2011.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical testing was not conducted to evaluate substantial equivalence. Usability testing was conducted in an animal model under a simulated use environment to validate the performance of the device. Callisyn FluidiTube® 2.7F Infusion Micro Catheters were compared to Progreat® 2.7 F Microcatheters in a healthy male Yorkshire swine. Operators successfully tracked the microcatheters into the right artery, the hepatic arteries, and the contralateral iliac artery, and injected the representative diagnostic (non-ionic contrast media Omnipaque 300), therapeutic (Heparin), and embolic material (embolic microspheres 500-700µm) through each microcatheter into the hepatic arteries as required by the protocol. Both Operators rated all test and control microcatheters as acceptable for:

- Ability to flush the packaging hoop and remove the microcatheter from the hoop without damage
- Ability to track the microcatheter through all three vessels and visualize them fluoroscopically
- Compatibility with the guidewire (0.014 in the RCA, 0.021 in the hepatic artery, and 0.018 in the iliac artery)
- Ability to visualize the device under fluoroscopy
- Compatibility 1mL of heparin, 2mL of non-dilute contrast media, and 1mL of 500-700µm embolic microspheres when injected into the hepatic artery
- Integrity, with no kinking or damage to the tip

There was no damage to the catheters noted, no vascular dissection was observed, and no thrombus was observed on any catheter when removed from the animal.

After a thorough assessment of all test article performance features, including use in conjunction with common ancillary diagnostic and therapeutic products, both Operators determined that all study protocol specified acute performance requirements of the FluidiTube® were successfully met for this study and it is comparable to the Terumo Progreat® 2.7Fr Microcatheters predicate device.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The Indications for Use, overall design, technological and performance characteristics of the FluidiTube® and Progreat® are substantially equivalent. Based on the data and evidence presented (e.g., performance testing, simulated use testing, etc.) for the FluidiTube®, Callisyn concludes that the device is substantially equivalent to the legally marketed micro catheter for its intended use. Differences between the proposed and predicate device do not raise any new issues of safety or effectiveness.