September 15, 2020

AngioDynamics, Inc.
Brandon Brackett
Senior Manager, Global Regulatory Affairs
26 Forest Street, Suite 200
Marlborough, Massachusetts 01752

Re: K202347
Trade/Device Name: UNIFUSE Infusion System with Cooper Wire
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: August 17, 2020
Received: August 18, 2020

Dear Brandon Brackett:

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

Gregory O'Connell
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202347

Device Name
UNIFUSE Infusion System with Cooper Wire

Indications for Use *(Describe)*
The UNIFUSE Infusion System with Cooper Wire is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY FOR THE "UNIFUSE INFUSION SYSTEM WITH COOPER WIRE"

Date Prepared: September 15, 2020

## Sponsor

Angiodynamics, Inc.
26 Forest Street
Marlborough, MA 01752
USA

## Regulatory Contact

**Brandon M. Brackett, RAC**
Senior Manager, Global Regulatory Affairs
AngioDynamics, Inc.
Telephone: 1-508-658-7984
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## Subject Device

| | |
|---|---|
| **Trade Name:** | UNIFUSE Infusion System with Cooper Wire |
| **Common Name:** | Infusion Catheter |
| **Regulation Number:** | 21CFR870.1210 |
| **Regulation Name:** | Catheter, Continuous Flush |
| **Regulatory Class:** | Class 2 |
| **Product Code:** | KRA |
| **Classification Panel:** | Cardiovascular Devices |

## Predicate Device

| | |
|---|---|
| **510(k) Reference** | **K192864** |
| **Trade Name:** | UNI*FUSE™ Infusion System with Cooper Wire |
| **Common Name:** | Infusion Catheter |
| **Regulation Number:** | 21CFR870.1210 |
| **Regulation Name:** | Catheter, Continuous Flush |
| **Regulatory Class:** | Class 2 |
| **Product Code:** | KRA |
| **Classification Panel:** | Cardiovascular Devices |

## Purpose

The purpose of this Special 510(k) is to introduce into commercial distribution a slight expansion of the UNIFUSE Infusion Catheter with Cooper Wire devices recently cleared under predicate 510(k) **K192864**; specifically, to expand the range of available configurations to include those with 10cm and 15cm "infusion segment lengths". This would be an addition to those 2cm and 5cm "infusion segment length" configurations recently cleared via that predicate 510(k), and in sum would expand the current range of "infusion segment length" options as follows:

- **Current range of "Infusion Segment Length" options (via predicate K192864)**: 2cm, 5cm
- **Proposed range of "Infusion Segment length" options**: 2cm, 5cm, 10cm, 15cm

Aside from this "infusion segment length" difference, there are no other modifications being proposed to the device – catheter overall length, diameter, device materials, Indications for Use, device labeling, and all other device attributes remain identical to those cleared via predicate 510(k) K192864.

## Device Description

The proposed UNIFUSE Infusion System with Cooper Wire devices are single-lumen, nylon catheters with longitudinal slits located at 90° intervals around the distal end of the catheter for fluid delivery. An occluding ball wire (or occlusion guidewire) provides end-hole occlusion during fluid delivery. The catheters are available in 4F and 5F diameters and overall lengths of 90cm and 135cm. Additionally, they are available in multiple infusion segment lengths, including 2cm, 5cm, 10cm, and 15cm lengths – the latter two of which are the subject of this proposal. It is also worth noting that the overall length of each catheter remains the same no matter the length of the infusion segment. The active infusion area can be identified under imaging by means of radiopaque markers on the catheter shaft at the distal and proximal ends of the infusion segment. As shown in Table 1 below, all of these characteristics are substantially equivalent to those of the predicate devices.

The proposed UNIFUSE Infusion System with Cooper Wire devices are intended for administration of fluids such as thrombolytics and contrast media into vessels that are impacted by thrombus, including the peripheral and pulmonary artery vasculature. Given the minimal physical differences of the vessels for which the device is intended to access (e.g. diameter, structure, tortuousness), the operating principle mechanism of action, and intended use is the same independent of anatomical location, use in the pulmonary artery is equivalent to other areas of the vasculature that the device is currently indicated for.

## Indications for Use/Intended Use

The UNIFUSE Infusion System with Cooper Wire is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature.

## Comparison of Similarities and Differences in Technological Characteristics and Performance

The proposed UNIFUSE Infusion System with Cooper Wire and the predicate UNIFUSE Infusion System with Cooper Wire (K192864) are identical to one another (and therefore substantially equivalent) in all terms, not limited to design, materials of manufacture, specifications, dimensions, Indications for Use, and sizes and/or configurations, as depicted in the comparison via Table 1 below. The sole difference is the proposed 10cm and 15cm "infusion segment length" attribute.

**Table 1: Comparison of Similarities and Differences in Technological Characteristics and Performance Proposed UNIFUSE Infusion System with Cooper Wire vs. Predicate UNIFUSE Infusion System with Cooper Wire (K192864)**

| | Proposed UNIFUSE Infusion System with Cooper Wire | Predicate UNIFUSE Infusion System with Cooper Wire (K192864) | Comparison |
|---|---|---|---|
| ProCode | KRA | KRA | Identical |
| Regulation Number | 21CFR870.1210 | 21CFR870.1210 | Identical |
| Regulation Name | Catheter, Continuous Flush | Catheter, Continuous Flush | Identical |
| Regulatory Class | Class 2 | Class 2 | Identical |
| Indications for Use | The UNIFUSE Infusion System with Cooper Wire is intended for the administration of fluids, | The UNIFUSE Infusion System with Cooper Wire is intended for the administration of fluids, | Identical |

| Table 1: Comparison of Similarities and Differences in Technological Characteristics and Performance<br>Proposed UNIFUSE Infusion System with Cooper Wire vs.<br>Predicate UNIFUSE Infusion System with Cooper Wire (K192864) | | | |
|---|---|---|---|
| | Proposed UNIFUSE Infusion System with Cooper Wire | Predicate UNIFUSE Infusion System with Cooper Wire (K192864) | Comparison |
| | including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature. | including thrombolytic agents and contrast media, into the peripheral and pulmonary artery vasculature. | |
| Catheter Diameter (F) | 4F, 5F | 4F, 5F | Identical |
| Catheter Length (cm) | 90cm, 135cm | 90cm, 135cm | Identical |
| Catheter Infusion Segment Length (cm) | 2cm, 5cm | 2cm, 5cm, 10cm, 15cm | Substantially Equivalent |
| Materials | All materials are commonly used for this type of medical device and are biocompatible in accordance with ISO 10993-1. | All materials are commonly used for this type of medical device and are biocompatible in accordance with ISO 10993-1. | Identical |

Furthermore, the proposed UNIFUSE Infusion System with Cooper Wire devices and predicate UNIFUSE Infusion System with Cooper Wire devices are incorporative of the identical operating principle, mechanism of action, intended use, and Indications for Use as one another (in addition to exhibiting identical overall design, materials of manufacture, sizes/configurations, and all other device attributes). Based upon the conclusions above, all previous biocompatibility, sterilization, shelf-life, and general performance testing supporting the predicate UNIFUSE Infusion System with Cooper Wire devices remains supportive of the proposed UNIFUSE Infusion System with Cooper Wire devices – the sole difference is that AngioDynamics, Inc. executed the same "human factors" testing conducted in support of K192864, in order to evaluate the 10cm and 15cm "infusion segment length" configurations proposed herein.

## Comparison of Performance Data

As touched on above, the proposed UNIFUSE Infusion System with Cooper Wire devices and predicate UNIFUSE Infusion System with Cooper Wire devices are the same device as one another, and as a result the performance testing that AngioDynamics, Inc. has on file for the predicate devices remains supportive of the proposed devices (the sole difference being the "human factors" testing executed on the proposed 10cm and 15cm "infusion segment length" configurations). Please refer to Table 2, below:

| Table 2: Summary of Performance Testing<br>Proposed and Predicate UNIFUSE Infusion System with Cooper Wire |
|---|
| -Dimensional Verification<br>-Length Sufficiency<br>-Catheter Hub-to-Catheter Shaft Connection Compatibility<br>-Catheter-to-Guidewire Compatibility<br>-Catheter-to-Introducer Sheath Compatibility<br>-Catheter Tip Radius<br>-Catheter Infusion |

| Table 2: Summary of Performance Testing<br>Proposed and Predicate UNIFUSE Infusion System with Cooper Wire |
|---|
| -Slit Pattern Radiopacity |
| -Catheter Degradation |
| -Catheter Pressure |
| -Catheter-to-Occlusion Wire Configuration (Slow Infusion Compatibility) |
| -Catheter/Accessory Compatibility |
| -Catheter/Fluid Compatibility |
| -Catheter Hub-to-Shaft Joint Kink Resistance |
| -Occlusion Wire Flexibility |
| -Occlusion Wire Flow |
| -Occlusion Wire Seal |
| -Hub-to-Wire Bond/Connection |
| -Distal Spring Tip-to-Mandrel Connection |
| -Occlusion Wire Withdrawal |
| -Human Factors Testing |

Human Factors Testing: In support of predicate 510(k) K192864, AngioDynamics, Inc. had conducted a human factors study on the UNIFUSE Infusion System with Cooper Wire configurations proposed therein. Specifically, Angiodynamics, Inc. solicited the participation of multiple practicing physicians experienced in the use and placement of infusion catheters to evaluate use of the devices on a simulated-use vascular model. The goal of the testing was to demonstrate the following:

- The devices are able to be navigated-to and used-within the pulmonary artery vasculature;
- The infusion segments are able to be clearly imaged under imaging (and thus confirmed to reside completely within the pulmonary artery vasculature);
- The Directions for Use include adequately detailed instructions in order to enable users to accurately and reliably place and use the device(s) within the pulmonary artery vasculature.

This same human factors testing was therefore executed on the 10cm and 15cm "infusion segment length" configurations proposed herein. Additionally, the predicate 2cm and 5cm "infusion segment length" configurations were also tested again as a means of directly comparing the proposed and predicate devices side-by-side and further demonstrating that these proposed configurations are acceptable for the pulmonary artery vasculature intended usage. To that end, it is confirmed that the results did show that the proposed 10cm and 15cm "infusion segment length" configurations are able to navigate the vasculature, be placed and used within the pulmonary artery, and have their location confirmed under imaging (e.g. fluoroscopy) – the same conclusions arrived at for those cleared via predicate 510(k) K192864. These determinations justify the expansion of the cleared configurations to include these 10cm and 15cm "infusion segment length" options.

## 510(k) Summary Conclusions

In conclusion, assessment of the similarities and differences of the proposed and predicate UNIFUSE Infusion System with Cooper Wire devices are identical and thus substantially equivalent to one another; specifically:

- The proposed and predicate device have the identical ProCode, Regulation Number, Regulation Name, and Regulatory Class as one another;
- The proposed and predicate device have identical Indications for Use and/or Intended Uses;

- The proposed and predicate devices incorporate the identical operating principle, mechanism of action, and are intended for the same patient populations; and,
- The proposed and predicate employ an identical overall design, materials of manufacture, performance testing, sizes, and configurations, aside from the 10cm and 15cm "infusion segment length" options being proposed herein.

Additionally, results of human factors testing on the proposed UNIFUSE Infusion System with Cooper Wire provide further evidence that the devices are able to be used in the pulmonary artery vasculature, as are the predicate devices. Lastly, the Special 510(k) was determined to be the most appropriate pathway for premarket notification based upon having met the criteria for such a submission type via FDA's Guidance Document, "*The Special 510(k) Program – Guidance for Industry and Food and Drug Administration Staff*" (September 13, 2019).

The sum of these evaluations and determinations lead AngioDynamics, Inc. to conclude that substantial equivalence has been demonstrated, and that the existing data, additional testing, and clinical evaluation determinations have confirmed that there are no new questions of safety or effectiveness.