November 22, 2021

Angiodynamics, Inc.
Brandon Brackett
Manager, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K192864
Trade/Device Name: UNI*FUSE Infusion System with Cooper Wire
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Brandon Brackett:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 1, 2020. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.11.22 13:42:55 -05'00'

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

June 1, 2020

Angiodynamics, Inc.
Brandon Brackett
Manager, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K192864
Trade/Device Name: UNI*FUSE™ Infusion System with Cooper Wire
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 2, 2020
Received: April 3, 2020

Dear Mr. 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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.06.01 13:44:17 -04'00'

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)*
K192864

Device Name
UNI*FUSE™ Infusion System with Cooper Wire

Indications for Use *(Describe)*
The UNI*FUSE™ 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.

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510(k) Summary
For the Angiodynamics, Inc. UNI*FUSE™ Infusion System with Cooper Wire
Date Prepared: June 1, 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
Facsimile: 1-508-658-7976
Email: bbrackett@angiodynamics.com

Subject Device

Trade Name:	Angiodynamics, Inc. 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

Predicate Device

510(k) Reference	**K183290**
Trade Name:	Thrombolex, Inc. Bashir™ and Bashir™ N-X Endovascular Catheters
Common Name:	Infusion Catheter
Regulation Number:	21CFR870.1210
Regulation Name:	Catheter, Continuous Flush
Regulatory Class:	Class 2
Product Code:	KRA
Classification Panel:	Cardiovascular Devices

Reference Device

510(k) Reference	**K163356**
Trade Name:	Angiodynamics, Inc. PULSE*SPRAY™ and UNI*FUSE™ Infusion Catheters
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 intent of this Traditional 510(k) is to propose a modification to the UNI*FUSE™ Infusion System with Cooper Wire Indications for Use statement, incorporative of a clarification being made in order to specify the pulmonary artery as a vessel indicated for device access. The UNI*FUSE™ Infusion System with Cooper Wire overall design is not changing as a result of this modification. This clarification is being made in response to the clinical use of Infusion Catheters in the pulmonary artery vasculature, identified as a usage primarily via available medical literature.

Device Description

The proposed UNI*FUSE™ 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 and 5cm lengths. 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 4 below, all of these characteristics are substantially equivalent to those of the predicate devices. Additionally, all of these characteristics are identical when comparing the proposed to the reference devices, as shown in Table 5.

The proposed UNI*FUSE™ 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 UNI*FUSE™ 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 UNI*FUSE™ Infusion System with Cooper Wire and the predicate Bashir™ N-X Endovascular Catheter Model 7200 are substantially equivalent to one another in terms of design, materials of manufacture, specifications, dimensions, Indications for Use, and sizes and/or configurations, as depicted in the comparison via Table 4 below:

Table 4: Comparison of Similarities and Differences in Technological Characteristics and Performance Proposed UNI*FUSE™ Infusion System with Cooper Wire vs. Predicate Bashir™ N-X Endovascular Catheter Model 7200 (K183290)

	Proposed UNI*FUSE™ Infusion System with Cooper Wire	Predicate Bashir™ N-X Endovascular Catheter Model 7200 (K183290)	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

Table 4: Comparison of Similarities and Differences in Technological Characteristics and Performance Proposed UNI*FUSE™ Infusion System with Cooper Wire vs. Predicate Bashir™ N-X Endovascular Catheter Model 7200 (K183290)			
	Proposed UNI*FUSE™ Infusion System with Cooper Wire	Predicate Bashir™ N-X Endovascular Catheter Model 7200 (K183290)	Comparison
Indications for Use	The UNI*FUSE™ 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.	The Bashir™ N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.	Substantially Equivalent
Catheter Diameter (F)	4F, 5F	7F	Substantially Equivalent
Catheter Length (cm)	90cm, 135cm	92.5cm	Substantially Equivalent
Catheter Infusion Segment Length (cm)	2cm, 5cm	12.5cm	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.	Substantially Equivalent

Additionally, these attributes are identical when comparing the proposed UNI*FUSE™ Infusion System with Cooper Wire to the reference UNI*FUSE™ Infusion Catheter, as shown in Table 5 below:

Table 5: Comparison of Similarities and Differences in Technological Characteristics and Performance Proposed UNI*FUSE™ Infusion System with Cooper Wire vs. Reference UNI*FUSE™ Infusion Catheter (K163356)			
	Proposed UNI*FUSE™ Infusion System with Cooper Wire	Reference UNI*FUSE™ Infusion Catheter (K163356)	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 UNI*FUSE™ 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.	The UNI*FUSE™ Infusion System is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature.	Identical *(Aside from proposed modification)*
Catheter Diameter (F)	4F, 5F	4F, 5F	Identical
Catheter Length (cm)	90cm, 135cm	45cm, 90cm, 135cm	Substantially Equivalent
Catheter Infusion Segment Length (cm)	2cm, 5cm	2cm, 5cm, 10cm, 15cm, 20cm, 30cm, 40cm, 50cm	Substantially Equivalent

Table 5: Comparison of Similarities and Differences in Technological Characteristics and Performance Proposed UNI*FUSE™ Infusion System with Cooper Wire vs. Reference UNI*FUSE™ Infusion Catheter (K163356)			
	Proposed UNI*FUSE™ Infusion System with Cooper Wire	Reference UNI*FUSE™ Infusion Catheter (K163356)	Comparison
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 UNI*FUSE™ Infusion System with Cooper Wire devices and predicate Bashir™ N-X Endovascular Catheter Model 7200's are incorporative of the same operating principle, mechanism of action, and intended use as one another (in addition to exhibiting substantial equivalence in terms of the overall design, materials of manufacture, sizes/configurations, and Indications for Use as shown above). Lastly, there are no changes being made to the UNI*FUSE™ Infusion System with Cooper Wire devices as compared to that cleared via reference 510(k) K163356. As a result, all previous biocompatibility, shelf-life, performance, and other testing identified within K163356 remains applicable to the proposed version.

Comparison of Performance Data

Angiodynamics, Inc. has also compared the performance testing that the Bashir™ N-X Endovascular Catheter Model 7200 was subjected to in support of its clearance, to that which the proposed UNI*FUSE™ Infusion System with Cooper Wire has been previously subjected to. While each battery of testing is not identical in a 1:1 nature, they are substantially equivalent to one another in that they fully test the functions of each device. Please refer to Table 6, below:

Table 6: Comparison of Performance Testing Proposed UNI*FUSE™ Infusion System with Cooper Wire vs. Bashir™ N-X Endovascular Catheter Model 7200 (K183290)	
Proposed UNI*FUSE™ Infusion System with Cooper Wire	Bashir™ N-X Endovascular Catheter Model 7200 (K183290)
-Dimensional Verification -Length Sufficiency -Catheter Hub-to-Catheter Shaft Connection Compatibility -Catheter-to-Guidewire Compatibility -Catheter-to-Introducer Sheath Compatibility -Catheter Tip Radius -Catheter Infusion -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	-Kink Radius -Trackability -Advancement Force -Slider Actuator -Catheter Retraction -Radial Force -Delivery Flow-Rate -Infusion Pressure at Various Flow Rates -Infusion Pressure with Pulse Spray -Pressure Measurement Through Central Lumen -Guidewire Compatibility -Dimensional Verification -Compliance of Injection Hubs -Air Leakage -Fluid Leakage -Stress Cracking -Resistance to Separation -Torque Strength -Corrosion Resistance -Joint Tensile Strength -Particulate Generation

In addition to the performance testing summarized above, Angiodynamics, Inc. has also conducted a human factors study on the proposed UNI*FUSE™ Infusion System with Cooper Wire. Specifically, Angiodynamics, Inc. solicited the participation of multiple practicing physicians experienced in the use and placement of infusion catheters to evaluate the proposed UNI*FUSE™ Infusion System with Cooper Wire on a simulated-use vascular model. The results of this testing demonstrated the following:

- The UNI*FUSE™ Infusion System with Cooper Wire configurations proposed via this submission are able to be navigated-to and used-within the pulmonary artery vasculature;
- The infusion segments of the UNI*FUSE™ Infusion System with Cooper Wire configurations proposed via this submission are able to be clearly imaged under fluoroscopy (and thus confirmed to reside completely within the pulmonary artery vasculature);
- The Directions for Use proposed for the UNI*FUSE™ Infusion System with Cooper Wire provides adequately detailed instructions in order to enable users to accurately and reliably place and use the device(s) within the pulmonary artery vasculature.

As a means of further validating the conclusions of the human factors study, Angiodynamics, Inc. also conducted an in-house "bench test" version of the study. The results of the in-house testing corroborated those of the human factors study summarized in the dialogue above, and the cumulative results demonstrate that the proposed UNI*FUSE™ Infusion System with Cooper Wire configurations are able to navigate the vasculature, be placed and used within the pulmonary artery, and confirm their location under imaging (e.g. fluoroscopy). These determinations further justify the Indications for Use modification proposed via this submission.

Clinical Literature Evaluation and Determinations

AngioDynamics, Inc. has assessed a variety of publicly available articles and other literature to identify instances of vasculature damage/endothelial cell destruction resulting from the use of various catheters (including infusion catheters) in the pulmonary artery vasculature. While the articles have varying endpoints, each study does document the other possible effects the device may pose during use (i.e. risks, complications, and other consequences) such that the risks and complications related to given devices and/or therapies are also known. None of the risks and complications identified related to pulmonary artery (or other vessel) damage and/or injury. This leads AngioDynamics, Inc. to conclude that there is a lack of evidence indicating the pulmonary artery vasculature to be more markedly prone to damage than other vessels for this application, and that the proposed Indications for Use does not increase existing risks OR introduce new risks. Secondarily, while the articles vary in the specific types of devices being used, infusion catheters (including the proposed UNI*FUSE™ Infusion System with Cooper Wire) are typically much smaller in diameter than other catheters being used, and therefore the other larger catheter types would represent a worst-case scenario in terms of hypothetical intrusiveness and potential for vessel damage. Please note: the clinical literature being cited and discussed is general in nature, and it is important to acknowledge that the subject UNI*FUSE™ Infusion Catheter with Cooper Wire device was not itself evaluated in the referenced studies. Additionally, the discussion developed from the clinical literature is intended to relate only to the UNI*FUSE™ Infusion Catheter with Cooper Wire devices, and only those with infusion segment lengths that have been confirmed to be completely contained within non-peripheral pulmonary arteries in a straight configuration (i.e. 2cm and 5cm infusion segment lengths).

Summary: AngioDynamics, Inc. has identified and reviewed relevant articles that discuss catheter-directed interventions and/or therapy for pulmonary embolism, and each summary includes discussion pertaining to related complications identified. The summary begins on the following page.

"Catheter-Directed Therapy in Acute Pulmonary Embolism with Right Ventricular Dysfunction: A Promising Modality to Provide Early Hemodynamic Recovery" (Dilektasli, A.G.; et al. – 2016)[1] evaluates the use of catheter-directed therapy (CDT) as an alternative to systemic thrombolysis (ST) in patients. Catheter-directed therapy is a percutaneous procedure used to dissolve thrombus by administering a lytic directly into said thrombus. The primary outcomes were mortality, clinical success, and complications. The study included 15 consecutive patients who underwent immediate catheter-directed therapy. An essential conclusion of the study was related to the complications of catheter-directed therapy, specifically, "*there were no technical complications, such as perforation of a cardiac/vascular structure, tamponade, or procedure-related death in our study.*" Instead, it continues by asserting that *"interventionalist experience is known to influence the technical success.*" In this article, that conclusion is contrasted against a statement made within a referenced article titled Goldhaber's "Percutaneous Mechanical Thrombectomy for Acute Pulmonary Embolism" (Goldhaber, S. 2007)[2] related to "percutaneous mechanical thrombectomy (PMT)" catheters", which states: "*the percutaneous mechanical thrombectomy catheter can perforate the pulmonary artery, cause massive distal embolization, or cause hemolysis*." The significance of these statements and their comparison to one another supports the following conclusion:

- The literature suggests that catheters that employ some type of mechanical component (or component that is in-addition-to a "typical" catheter design) may have a greater risk for the potential of vessel damage compared to catheters that do not.

"Catheter-Directed Therapy for the Treatment of Massive Pulmonary Embolism: Systematic Review and Meta-Analysis of Modern Techniques" (Kuo, W. et al. – 2009)[3] summarizes the authors' systematic review of modern techniques related to catheter-directed therapy for the treatment of massive pulmonary embolism; specifically, to evaluate the safety and effectiveness of modern catheter-directed therapy (CDT) as an alternative treatment for massive pulmonary embolism. 594 patients from 35 studies (6 prospective, 29 retrospective) were analyzed both for the clinical success rate associated with catheter-directed therapy, as well as the minor and major complications encountered during catheter-directed therapy treatment (along with the rates associated with each complication). The pooled clinical success rate from catheter-directed therapy was 86.5%, and the pooled risks of minor and major procedural complications were 7.9% and 2.4% respectively. Minor and major complications were listed by specific type of complication, and none were related to injury or damage to the pulmonary artery itself. The significance of this data is twofold:

1. It shows that catheter-directed treatment in the pulmonary artery vasculature is a treatment that has a high success rate attributed to it; and
2. It shows that the complications associated with catheter-based interventions in the pulmonary artery vasculature do not include – in either "minor" or "major" complication categories – damage and/or injury to the vessel itself.

"Catheter-Directed Interventions for Pulmonary Embolism" (Zarghouni, M; et al. – 2016)[4] is an analysis of the information and conclusions of numerous key studies related to pulmonary artery vasculature interventions, most notably (*see next page*):

[1] Dilektasli, A.G.; et al. – "Catheter-Directed Therapy in Acute Pulmonary Embolism with Right Ventricular Dysfunction: A Promising Modality to Provide Early Hemodynamic Recovery" (2016)
[2] Goldhaber, S. – "Percutaneous Mechanical Thrombectomy for Acute Pulmonary Embolism" (2007)
[3] Kuo, W.; et al. – "Catheter-Directed Therapy for the Treatment of Massive Pulmonary Embolism: Systematic Review and Meta-Analysis of Modern Techniques" (2009)
[4] Zarghouni, M.; et al. – "Catheter-Directed Interventions for Pulmonary Embolism" (2016)

- Piazza, et al. – "Prospective, Single-Arm, Multi-Center Trial of EkoSonic Endovascular System and Activase for Treatment of Acute Pulmonary Embolism – SEATTLE II Study" (2015)
- Kuo, et al. – "Pulmonary Embolism Response to Fragmentation, Embolectomy, and Catheter Thrombolysis – PERFECT Study" (2015)
- Kucher, et al. – "Ultrasound-Assisted Catheter Directed Thrombolysis for Acute Intermediate-Risk Pulmonary Embolism – ULTIMA Study" (2013)
- Meyer, et al. – "Pulmonary Embolism Thrombolysis – PEITHO Study" (2014)

The analysis outlines the number of patients involved in each study, the study type, the endpoints of each study, the arms of each study, and the findings/complications/etc. it also analyzes various types of catheter-directed therapies in the pulmonary artery vasculature, most notably "*Catheter-Directed Thrombolysis via Infusion Catheters*." It describes the benefits as well as the adverse aspects of each treatment option, and identifies the complications associated with each. Of the various options identified within the literature, none of the complications identified were related to vessel damage, endothelial cell destruction, or other types of complications synonymous with pulmonary artery vasculature injury. It concludes "*there has been a reemergence of interest in catheter-directed techniques. Newer guidelines employ CDI [catheter-directed intervention] in treatment protocols. CDI has become a vital to at many institutions.*"

510(k) Summary Conclusions

In conclusion, assessment of the similarities and differences of the proposed UNI*FUSE™ Infusion System with Cooper Wire and the predicate Bashir™ N-X Endovascular Catheter Model 7200 led Angiodynamics, Inc. to determine that the two are 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 substantially equivalent Indications for Use and/or Intended Uses;
- The proposed and predicate devices each employ the same operating principle, mechanism of action, and are intended for the same patient populations; and,
- The proposed and predicate exhibit equivalent overall design, materials of manufacture, performance testing, sizes, and configurations.

Additionally, results of human factors testing on the proposed UNI*FUSE™ Infusion System with Cooper Wire provide further evidence that the devices are able to be used in the pulmonary artery vasculature. Lastly, evaluation of publicly available clinical literature leads AngioDynamics, Inc. to conclude that:

- There is a lack of evidence indicating the pulmonary artery vasculature to be more markedly prone to damage than other vessels for this application; and,
- The literature suggests that catheters that employ some type of mechanical component (or component that is in-addition-to a "typical" catheter design) may have a greater risk for the potential of vessel damage compared to catheters that do not.

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.