



November 22, 2021

Angiodynamics  
Brian Kunst  
Director of RA/QA  
266 Queensbury Ave.  
Queensbury, New York 12804

Re: K951509  
Trade/Device Name: Pulse\*Spray Infusion System  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy catheter  
Regulatory Class: Class II  
Product Code: QEY, KRA

Dear Brian Kunst:

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 16, 1995. 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](mailto:Gregory.Oconnell@FDA.HHS.gov).

Sincerely,

**Gregory W. O'Connell -S** Digitally signed by  
Gregory W. O'Connell -S  
Date: 2021.11.22  
13:47:07 -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



JUN 16 1995

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

Mr. Brian Kunst  
Director of Regulatory Affairs/  
Quality Assurance  
AngioDynamics™  
P.O. Box 993  
266 Queensbury Avenue  
Glens Falls, New York 12801

Re: K951509  
Pulse Spray Infusion System  
Regulatory Class: II (two)  
Product Code: 74 KRA  
Dated: March 31, 1995  
Received: April 3, 1995

Dear Mr. Kunst:  
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act

may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script that reads "Thomas J. Callahan". The signature is written in black ink and is positioned above the typed name.

Thomas J. Callahan, Ph.D.

Acting Director

Division of Cardiovascular,

Respiratory, and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

A handwritten number "2" in black ink, located in the lower right quadrant of the page.