SEP 2 3 2008

K081472

4.0 510(k) Summary

Date: May 19, 2008

Sponsor of the 510(k)

AngiodDynamics, Inc.
603 Queensbury Ave
Queensbury, NY 12801
Establishment Registration number 1319211
Contact: Brian Kunst, Vice President, Regulatory Affairs and Quality Assurance
518-798-1215, x1123

Device Identification:

Proprietary Name:	SmartPort CT Series Port Access Systems
Common Name:	Vascular access port
Classification Name:	Subcutaneous, implanted, intravascular infusion port & catheter
Classification Number:	21 CFR §880.5965
Classification Panel:	General Hospital
Product Code:	LJT
Regulatory Class:	II

Legally marketed device to which equivalence is claimed:

AngioDynamics SmartPort CT MP	510(k) K072375
AngioDynamics SmartPort CT	510(k) K062414
Horizon Medical Vortex Ports	510(k) K905841, K953529, K010189, K032557

Intended Use / Indications

The SmartPort CT Port Access System is indicated for any adult patient requiring repeated access of the vascular system or other selected body site, for the delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood.

The SmartPort CT Series ports are also indicated for power injection of CT contrast media.

Device Description

The SmartPort CT Series ports are Titanium or plastic, single or dual ports with a self sealing silicone rubber septum designed to maintain integrity after punctures with a non-coring needle. The port has a hollow area, or reservoir, under the septum through which fluid passes during infusion or aspiration.

The Vortex design features a proprietary reservoir with rounded walls giving it a toroidal shape. The outlet stem is located tangential to the reservoir wall allows fluid to pass between the reservoir and the catheter.

The SmartPort CT Series port systems offers models with catheters from 6.6FR to 12FR. The catheters contain radiopacifiers and have depth markings.

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Device comparison table

	AngioDynamics SmartPort CT Series Vortex Ports	**AngioDynamics SmartPort CT MP** K072375	**AngioDynamics SmartPort CT** K062414	**RITA Medical Systems (formerly Horizon Medical Products)** K905841, K953529, K010189, K032557
Intended use, power injection	Maximum 3 ml/sec or 5 ml/sec injection rate of contrast dye injected at up to 300 psi	Maximum 3 ml/sec injection rate of contrast dye injected at up to 300 psi.	Maximum 5 ml/sec injection rate of contrast dye injected at up to 300 psi.	Not indicated for power injection
Design	Port system with attachable catheter	Port system with attachable catheter, single.	Port system with attachable catheter, single.	Port system with attachable catheter, single or dual.
Port Material	Titanium or Plastic	Titanium	Titanium	Titanium or Plastic
Catheter Material	Polyurethane or Silicone	Polyurethane	Polyurethane or Silicone	Polyurethane or Silicone
Catheter Size	6.6-12 FR	5 FR	7.5-9.6 FR	6.6-12 FR
Shape	Round port system with tangential outlet	Round port system with tangential outlet	Round port system with tangential outlet	Round port system with tangential outlet
Septum Material	Silicone	Silicone	Silicone	Silicone
Pressure withstand, dynamic	300 PSI	300 PSI	300 PSI	Not Rated
Needles used for Access	19 or 20 Ga power injectable infusion set	19 or 20 Ga power injectable infusion set	19 or 20 Ga power injectable infusion set	19 or 20 Ga infusion set

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2008

Mr. Brian Kunst
ANGIODYNAMICS, Incorporated
603 Queensbury Avenue
Queensbury, New York 12804

Re: K081472
Trade/Device Name: SmartPort CT Series Port Access System
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: August 27, 2008
Received: August 29, 2008

Dear Mr. Kunst:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SmartPort CT Series Port Access System

Indications for Use:

The SmartPort CT Series Port Access System is indicated for any patient requiring repeated access of the vascular system for the delivery of medications, nutritional supplementation, fluids, blood, blood products, and the sampling of blood.

The SmartPort CT Series Port Access System is also indicated for power injection of contrast media at a maximum infusion rate of 3 ml/sec or 5 ml/sec when used with 20 Ga or 19 Ga power injectable infusion sets.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K981976