SECTION 4: 510(K) SUMMARY

MAY 2 4 2011

Sponsor/Submitter:	Arstasis, Inc. 1021 Howard Avenue, Suite C San Carlos, CA 94070
Contact Person:	Debra Cogan Director, Regulatory & Clinical Affairs Phone: (650) 508-1549 x273 Fax: (650) 594-4326
Date of Submission:	November 19, 2010
Device Trade Name:	Arstasis Dilator Adapter
Common Name:	Dilator Adapter
Device Classification:	Class II
Regulation Number:	21 CFR 870.1310
Classification Name:	dilator, vessel, for percutaneous catheterization
Product Code:	DRE
Predicate Device:	Prelude Sheath Introducer (K070159)
Device Description:	The Adapter is a sterile, single use device that is hollow and has a tapered increase in outer diameter on one end. This shape allows the Adapter to fill the excess space between .018" guidewires and dilators with larger inner diameters.
Indications for Use:	The Adapter is intended to allow the use of a .018" guidewire with a .035" or .038" guidewire compatible dilator up to 23cm in overall length.
Technological Characteristics	The Dilator Adapter is a polyethylene bump extrusion that fits into a .035"-.038" compatible vessel dilator with an internal diameter-sized-- to an .018" guidewire.
Performance Data	The Dilator Adapter was subjected to tensile testing to demonstrate that it met ISO11070-1998 specifications for dilators. The Adapter also underwent testing for dimensional specifications, design verification and validation including insertion forces and useability as assessed on a simulated clinical bench model.
Summary of Substantial Equivalence:	The Arstasis Dilator Adapter is substantially equivalent to the predicate device as confirmed through performance testing.

SECTION 3: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103421

Trade Name: Arstasis Dilator Adapter

Common Name: dilator, vessel, for percutaneous catheterization

Indications For Use: The Adapter is intended to allow the use of a .018" guidewire with a .035" or .038" guidewire compatible dilator up to 23cm in overall length.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103421

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 28 2011

Arstasis Inc.
c/o Ms. Debra Cogan
Director, Regulatory & Clinical Affairs
740 Bay Road
Redwood City, CA 94063

Re: K103421
Trade Name: Arstasis Dilator Adapter
Regulation Number: 21 CFR 870.1310
Regulation Name: Dilator, Vessel, for Percutaneous Catheterization
Regulatory Class: II (two)
Product Code: DRE
Dated: May 12, 2011
Received: May 13, 2011

Dear Ms. Cogan:

This letter corrects our substantially equivalent letter of May 24, 2011.

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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

Enclosure
Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103421

Trade Name: Arstasis Dilator Adapter

Common Name: dilator, vessel, for percutaneous catheterization

Indications For Use: "The Adapter is intended to allow the use of a .018" guidewire with a 0.035" or .038" guidewire compatible dilator up to 23 cm in overall length and to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures."

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Posted November 13, 2003)

(Division Sign-Off)
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