



August 7, 2015

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

Arstasis, Inc.  
Debra Cogan  
Regulatory Consultant  
6500 Kaiser Drive  
Suite 120  
Fremont, CA, 94555

Re: K151877  
Trade/Device Name: MicroTract Access System  
Regulation Number: 21 CFR 870.1310  
Regulation Name: Vessel dilator for percutaneous catheterization  
Regulatory Class: II  
Product Code: DRE  
Dated: July 7, 2015  
Received: July 9, 2015

Dear Ms. Cogan:

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.

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); 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 contact the Division of Industry and Consumer Education 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>. 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 <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 Industry and Consumer Education 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 -S**

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

**SECTION 1. INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): \_\_\_\_\_

Trade Name: MicroTract Access System

Common Name: dilator, vessel, for percutaneous catheterization

Indications For Use: The MicroTract Access System 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   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

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## SECTION 2. 510(k) SUMMARY

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| <b>Sponsor/Submitter:</b>                  | Arstasis, Inc.<br>650 Kaiser Rd<br>Fremont, CA 94555   |
| <b>Contact Person:</b>                     | Debra Cogan<br>Regulatory Consultant<br>Phone: (408) 515-0820<br><br>Fax: (650) 508-1567   |
| <b>Date of Submission:</b>                 | July 7, 2015   |
| <b>Device Trade Name:</b>                  | MicroTract Access System   |
| <b>Common Name:</b>                        | Dilator Adapter  |
| <b>Device Classification:</b>              | Class II   |
| <b>Regulation Number:</b>                  | 21 CFR 870.1310  |
| <b>Classification Name:</b>                | dilator, vessel, for percutaneous catheterization  |
| <b>Product Code:</b>                       | DRE  |
| <b>Primary Predicate Device:</b>           | Arstasis Dilator Adapter (K103421)   |
| <b>Secondary Predicate Device:</b>         | AXERA RX Access System (K140287)   |
| <b>Device Description:</b>                 | The MicroTract Access System contains a 20 gauge Access Needle, a 0.018" Guidewire, and a Dilator Adapter. The Dilator 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. |
| <b>Indications for Use:</b>                | The MicroTract Access System is intended to allow the use of a .018" guidewire with a .035" or .038" guidewire compatible dilator up to 23cm in overall length.  |
| <b>Technological Characteristics</b>       | The MicroTract Dilator Adapter is a polyethylene bump extrusion that fits into a .035"- .038" compatible vessel dilator with an internal diameter sized to 0.018" guidewire. The Access Needle is a 20 gauge diameter needle made of stainless steel. The guidewire is 0.018" diameter made of Nitinol with a Tungsten coil.                                     |
| <b>Performance Data</b>                    | The MicroTract Access System was subjected to tensile testing to demonstrate that it met ISO11070-1998 specifications for dilators. The System also underwent testing for dimensional specifications, design verification and validation including insertion forces and useability as assessed on a simulated clinical bench model.                              |
| <b>Summary of Substantial Equivalence:</b> | The MicroTract Access System is substantially equivalent to the predicate device as confirmed through performance testing.   |