510(k) Summary

Date Prepared:	March 27, 2013
Company:	Argon Medical 3600 SW 47th Ave. Gainesville, FL 32608 Facility Registration number: 1037610
Contact:	Jennifer Bonacci Regulatory Affairs Manager Phone: 352-519-5029 Fax: 352-338-0662 Email: jennifer.bonacci@argonmedical.com
Sterilization Site	STERIS Isomedix Services, Inc. 2072 Southport Road Spartanburg, SC 29306-6299, USA Facility Registration number: 1047843
Device trade name:	V•Stick™ Vascular Access Set
Device Common Name:	Vascular access set
Device classification:	Introducer, catheter Product code, DYB 21 CFR 870.1340 Class II
Legally marketed device to which the device is substantially equivalent:	K011790 MicroCruiser® Plus Introducer Set K091584 Merit MAK (Mini Access Kit) K851834 Manan GWI Guidewire Introducer
Description of the device:	The V•Stick™ Vascular Access Set assists in gaining vascular access for the placement of 0.035" and 0.038" guidewires into the vascular system using small needle access. It is composed of a 21ga puncture needle with and without silicone coating, and available with or without an echogenic tip. A coaxial introducer set with a 4F or 5F sheath and a standard or stiff 3F dilator is included. Finally a 0.018" stainless steel or Nitinol guidewire with a platinum or palladium alloy coil tip.
Indications for Use:	The V•Stick™ Vascular Access Sets intended for use in the introduction and placement of guidewires and/or catheters

Technological Characteristics:

The subject of this 510(k) is to provide an additional offering for the current V•Stick Vascular Access Set to include a 0.018" guidewire with a palladium/rhenium coil tip and a silicone coated 21ga puncture needle in addition to the existing co-axial introducer set.

The V•Stick Vascular Access Set is similar in design components, dimensions, and materials to the predicate devices. The MicroCruiser® [K011790], Merit MAK [K091584], and V•Stick are all available in the same French and 0.018" guidewire sizes. The lengths of the co-axial introducer, guidewire and puncture needle are identical. The materials found in all three sets are similar. The spring tip of the 0.018" guidewire is made of radiopaque material as is the guidewire tip in the predicate set.

The distal tip of the 21ga puncture needle may or may not have echogenic properties which are also true in the predicate sets. This needle is also provided with a silicone coating just as the predicate Manan Guidewire Introducer Needle [K851834].

The V•Stick Vascular Access Set, like the predicate devices, is compatible with guidewires with a maximum outer diameter of 0.038". All three access sets are sterilized in an ethylene oxide process and have similar sterile barrier packaging materials.

Substantial Equivalence:

The V•Stick Vascular Access Set has the same indications for use, technical characteristics, and materials as the MicroCruiser® Plus Introducer. The V•Stick Vascular Access Set has the same introducer needle with silicone coating as the Manan GWI Guide Wire Introducer and the same intended use. The V•Stick™ Vascular Access Set has the same 0.018" guidewire with palladium alloy coil tip as the Merit MAK® Mini Access Kit and the same intended use.

Performance tests (Non-Clinical):

The V•Stick Vascular Access Set is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and Indications for Use. The device design has been qualified through the following tests:

- Dimensional Verification
- Stiffness Comparison
- Radiopacity
- Sharpness
- Visual Inspection
- Weld Strength
- Ultrasound Visibility
- Tensile Strength

Biocompatibility testing per ISO 10993-1 was performed, consisting of the following tests:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Acute systemic toxicity
- Hemocompatibility

The results of this testing demonstrates that the V•Stick™ Vascular Access Set, is substantially equivalent to the predicate devices and did not raise new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 22, 2013

Argon Medical
C/O Jennifer Bonacci
Regulatory Affairs Manager
3600 Southwest 47th Avenue
Gainesville, FL 32608 US

Re: K130730
Trade/Device Name: V-Stick™ Vascular Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 17, 2013
Received: October 23, 2013

Dear Ms. Bonacci:

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 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. 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 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130730

Device Name
V•Stick™ Vascular Access Set

Indications for Use *(Describe)*
V•Stick™ Vascular Access Sets intended for use in the introduction and placement of guidewires and/or catheters

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*