DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 16, 2017

Stroke2Prevent B.V.
% Mr. Paul Dryden
Consultant/Manager
Promedic, LLC
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K170338
Trade/Device Name: A-View®
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: April 19, 2017
Received: April 21, 2017

Dear Mr. Dryden:

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K170338

Device Name

A-View®

Indications for Use *(Describe)*

A-View® is intended for use in conjunction with TEE investigation of the upper mediastinum in anesthetized patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View® is limited for use in adult patients.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Proprietary or Trade Name: A-View®

Common/Usual Name: Diagnostic Ultrasound Transducer

Classification: ITX – Diagnostic Ultrasound Transducer, CFR 892.1570

Predicate Device: Cordatec n.v. – A-View® - K070515

Device Description:
The A-View® is a catheter with an inflatable balloon that is inserted through an endotracheal tube of an anesthetized patient. Once inserted the balloon is inflated with saline. This inflated balloon is placed near the aortic arch so that when the clinician is performing a TEE (transesophageal echocardiography) procedure the saline filled balloon provides better contrast for an image.

Indications for Use:
A-View® is intended for use in conjunction with TEE investigation of the upper mediastinum in anesthetized patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View® is limited for use in adult patients.

Contraindications:
May not be used in case of severe respiratory failure, tracheomalacia or contraindications for the use of TEE (e.g. systemic tissue disease affecting the esophagus and/or trachea tissue to a degree not compatible with any aspect of TEE).

Device Comparison

Table 5.1 compares the subject device to the predicate

Feature	Predicate Cordatec A-View®	Proposed Device A-View®
Indications for Use	A-View Catheter is intended for use in conjunction with TEE investigation of the upper mediastinum in anesthetized patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View Catheters are limited for use in adult patients.	A-View® is intended for use in conjunction with TEE investigation of the upper mediastinum in anesthetized patients. They allow visibility of the distal ascending aorta by TEE and permit the condition of the ascending aorta to be evaluated before surgery. A-View® is limited for use in adult patients.
Patient Population	Adults	Adults
Environment of use	Hospitals and outpatient surgery facility where TEE is performed	Hospitals and outpatient surgery facility where TEE is performed

Feature	Predicate Cordatec A-View®	Proposed Device A-View®
Contraindications	May not be used in case of severe respiratory failure, tracheomalacia or contraindications for the use of TEE (e.g. systemic tissue disease affecting the esophagus and/or trachea tissue to a degree not compatible with any aspect of TEE).	May not be used in case of severe respiratory failure, tracheomalacia or contraindications for the use of TEE (e.g. systemic tissue disease affecting the esophagus and/or trachea tissue to a degree not compatible with any aspect of TEE).
Provided sterile	Yes – EO	Yes - EO
Compatibility with	Endotracheal tubes $\geq$ 7.0 mm ID	Endotracheal tubes $\geq$ 7.0 mm ID
Balloon filled	Sterile saline	Sterile saline
Depth Markings	At 24 cm	At 24 cm and 28 cm
Main Balloon diameter	29 mm	29 mm
Pilot Balloon	Provides visual indicator of inflation of main balloon	Provides visual indicator of inflation of main balloon Made slightly larger than predicate
Catheter shaft – ID/OD	2 mm / 4 mm	2 mm / 4 mm
Total overall length	1065 mm	1065 mm
Shelf-Life	3 years	4 years
Biocompatibility	Externally Communicating / Tissue And Surface Contact / Mucosal Membrane Limited duration (<24 hours)	Externally Communicating /Tissue And Surface Contact / Mucosal Membrane Limited duration (<24 hours) Cytotoxicity Sensitization Intracutaneous reactivity Acute Systemic Toxicity
Performance Testing		Leakage Balloon inflation Bond strength Flexibility of tubing Kink test Torque Tensile strength Drop test

Substantial Equivalence Discussion

Indications for Use / Patient Population / Environment of Use: A comparison of Indications for Use concludes that they are similar.
Discussion: There is no difference in indications for use, patient population and environment of use.

Prescriptive: Both are prescription devices.
Discussion: There are no differences.

Design and Technology: The design and employed technology of both devices is similar, with similar components, methods of construction, and operation.
Discussion: There is no difference is in design and technology.

Performance and Specifications: The testing related to performance and specifications demonstrate that both devices perform the same functions using the same technology.

Discussion: There are no differences between both devices, thus they can be found substantially equivalent.

Compliance with Standards: We utilized several recognized standards in the evaluation of the subject device.

- ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity (2009)
- ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization (2010)
- ISO 10993-11, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity (2006)

Discussion: We have evaluated performance to the closest available standards and the results support the determination of substantial equivalence.

Non-clinical Performance Testing:

Bench Tests: We have performed bench tests and found that the A-View® met all performance requirements and specifications and was found to be equivalent in comparison to the predicate. The test included:

- Leakage
- Balloon inflation
- Bond strength
- Flexibility of tubing
- Kink test
- Torque
- Tensile strength
- Drop test
- Tests real-time aged devices

Biocompatibility: We have performed ISO 10993-1 testing as the materials in patient of the A-View® as:

- Surface Contact / Mucosa membrane / Limited duration of use (<24 hours)

And

- Externally communicating / Tissue / Dentin / Bone / Limited duration of use (< 24 hours)

Test that was performed included:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity / Irritation
- Acute Systemic Toxicity even though it is not required

Differences

There are slight differences between the predicate and the proposed device. The differences are:

- Pilot balloon was modified in size and shape for easier viewing by the clinician
  - This change has no performance change, only that it is larger than the predicate
- Materials – some materials were changed
  - The materials were evaluated via ISO 10993 testing
- Device marking
  - The proposed device has an additional marking at 28 cm on the main shaft
    - This assists the user in depth placement

Substantial Equivalence Conclusion

Based upon the foregoing performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we believe we have demonstrated that the A-View® is substantially equivalent to the predicate device.