October 16, 2019

Abbott Medical
Gabrielle Zaeska
Regulatory Affairs Manager
5050 Nathan Lane
Plymouth, Minnesota 55442

Re: K190581
Trade/Device Name: Amplatzer™ Trevisio™ Intravascular Delivery System
Regulation Number: 21 CFR 870.125021 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 5, 2019
Received: March 6, 2019

Dear Gabrielle Zaeska:

This letter corrects our substantially equivalent letter of April 5, 2019.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190581

Device Name

Amplatzer™ Trevisio™ Intravascular Delivery System

Indications for Use *(Describe)*

The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter:	Abbott Medical 5050 Nathan Lane Plymouth, MN 55442
Contact Person:	Gabrielle Zaeska Manager, Regulatory Affairs Phone: 651-756-5691 Fax: 651-756-5744 E-mail: Gabrielle.Zaeska@abbott.com
Date Prepared:	March 1, 2019
Trade Name:	Amplatzer™ Trevisio™ Intravascular Delivery System
Common Name:	Catheter Delivery System
Classification:	Class II, 21 CFR 870.1250 Catheter, Percutaneous
Product Code:	DQY
Predicate Device(s):	AMPLATZER TorqVue Delivery System (K072313, cleared 02 November 2007)

Device Description:

The Amplatzer™ Trevisio™ Intravascular Delivery System (ATV) is an extension of the Amplatzer TorqVue Delivery System (ITV) product line. This device is also referred to as "Flex Cable" on internal Abbott Medical documentation.

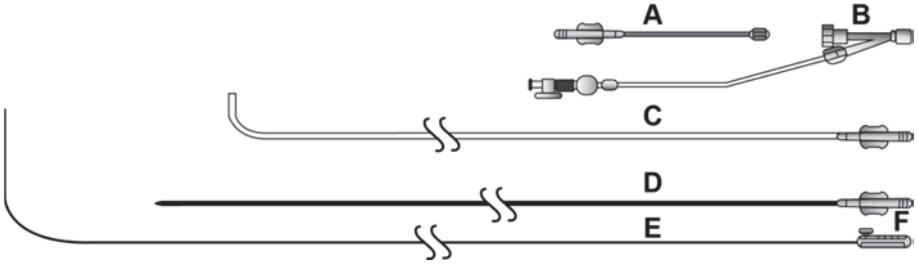
The Trevisio Delivery System components are identical to the cleared ITV device which include a delivery system sheath, dilator, loader, hemostasis valve with extension tube and stopcock, delivery cable and plastic vise.

In comparison to ITV, the cable component of the Trevisio Delivery System has been designed with a flexible distal tip to reduce bias when delivering an implant device; allowing physicians to more accurately assess placement prior to device release.

Like ITV, the distal end of the sheath is offered in a 45° curve and is radiopaque for visibility under fluoroscopy. **Figure 1** illustrates the delivery system and identifies the following essential components

- Loader (A) -introduces an Amplatzer device into the sheath
- Hemostasis valve (B)with extension tube and stopcock-allows flushing of the delivery system and controls blood backflow
- Delivery System Sheath (C) -provides a pathway through which an Amplatzer device is delivered
- Dilator (D) -eases penetration of tissue and minimizes vessel trauma
- Delivery Cable (E) -attaches to the device to control its movement through the sheath
- Plastic Vise (F) -attaches to the delivery cable and serves as a handle for disconnecting (unscrewing) the delivery cable from the device.

Figure 1. Amplatzer™ Trevisio™ Delivery System Components



Intended Use: The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Comparison to predicate: The Amplatzer Trevisio Intravascular Delivery System is an extension of the Amplatzer TorqVue Delivery System (K072313) product line. The current TorqVue Delivery System includes a delivery system sheath, dilator, loader, hemostasis valve, delivery cable, and plastic vise for the delivery of Amplatzer occlusion devices. The Trevisio Delivery System components are identical to the TorqVue Delivery System with the exception of a more flexible delivery cable with device positioning mark. The differences between the subject Trevisio device (ATV) and predicate TorqVue Delivery System (ITV) are:

- The ATV device is only offered in 45° sheath curve
- The ATV delivery cable includes more flexible distal tip
- The ATV delivery cable includes a proximal mark to provide physician with an indication of when the device is nearing the tip of the delivery sheath, reducing the need for fluoroscopy.
- The ATV packaging will incorporate a protective tube and modified backing card tabs to support the cable.

The intended use of the Amplatzer Trevisio Delivery System is identical to that of the Amplatzer TorqVue Delivery System; there has been no change as a result of the proposed modifications.

Functional and Safety Testing:

The new cable design and system were tested to ensure the device performs as intended. Because there are no changes to the ITV components besides the enhanced delivery cable, bench and laboratory testing was not performed on those individual components which remain unchanged. The following testing of the new cable and system level testing was performed:

- Delivery Cable Distal Flexibility
- Delivery Cable Outer Diameter
- Delivery Cable Length
- Delivery Cable Leak
- Sheath Material Separation
- Torque Strength
- Tensile Strength
- Delivery Cable Advancement force
- Marker Visibility
- Deploy and Recapture
- Device Release
- Shelf Life
- Biocompatibility
- Corrosion

Conclusion:

Abbott Medical considers the Amplatzer Trevisio Intravascular Delivery System to be substantially equivalent to the TorqVue Delivery System. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.