December 21, 2017

Delta Med SpA
% Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, N 10
Rome, 00153
ITALY

Re: K171530
Trade/Device Name: Deltaven Closed I.V. Catheter Systems
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ,
Dated: November 21, 2017
Received: November 24, 2017

Dear Roger Gray:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171530

Device Name
Deltaven Closed I.V. Catheter Systems

Indications for Use *(Describe)*

Deltaven Closed I.V. Catheter systems are catheters for short-term peripheral venous access that allow the collection of blood samples and administration of fluids intravascularly.
Deltaven Closed I.V. Catheter systems are equipped with a passive system for the prevention of accidental needlestick injuries.
Blood is contained within the device during the catheter insertion process, aiding the prevention of blood exposure.
The device can be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.
Deltaven Closed I.V. Catheter systems 16-24 gauge catheters are suitable for use with pressure injectors rated for a maximum of 330 psi when the access ports and stopcocks are removed and a direct connection is made with the proximal luer lock connector.
Deltaven Closed I.V. Catheter systems 26G are not suitable for the administration at high pressure.

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.

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K171530 510(K) SUMMARY

Submitter: Delta Med S.p.A
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Preparation Date: December 18, 2017

Trade Name: Deltaven Closed I.V. Catheter Systems

Common or Usual Name: Intravascular Catheter

Regulation Name: Intravascular Catheter

Regulation Number: 21 CFR 880.5200

Product Code: FOZ

Device Class: Class II

Primary Predicate Device: K102520; BD Nexiva Closed IV Catheter System

Device Description:
The devices consist of an over-the-needle, peripheral intravascular catheter made of polyurethane, integrated extension tubing with Luer lock adaptor and slide clamp. The devices are also equipped with a Luer lock final adaptor (single entry version) or a Y Luer lock final adapter (dual entry version).

Deltaven Closed I.V. Catheters are available in five versions, as follows:

- Deltaven XiV Max
- Deltaven XiV Max Y
- Deltaven XiV Max SC
- Deltaven XiV Max Y-NL
- Deltaven XiV Max SC-NL

The same versions are available with the needle provided with a notch along its surface that permits the early visualization of blood return inside the catheter tube. This version is generally named as Deltaven XiV Max Fast Flash and is available in five versions, as follows**:**

- Deltaven XiV Max Fast Flash
- Deltaven XiV Max Y Fast Flash
- Deltaven XiV Max SC Fast Flash
- Deltaven XiV Max Y- NL Fast Flash
- Deltaven XiV Max SC-NL Fast Flash

The devices provided with single entry Luer lock adaptors are also equipped with:

- Luer lock white cap
- 3 way stopcock
- 3 way stopcock and needleless valve

The devices provided with dual entry Luer lock adaptors are also equipped with:

- Luer lock white cap
- Needleless valve connector

Indications for Use:
Deltaven Closed I.V. Catheter systems are catheters for short-term peripheral venous access that allow the collection of blood samples and administration of fluids intravascularly.

Deltaven Closed I.V. Catheter systems are equipped with a passive system for the prevention of accidental needlestick injuries.

Blood is contained within the device during the catheter insertion process, aiding the prevention of blood exposure. The device can be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

Deltaven Closed I.V. Catheter systems 16-24 gauge catheters are suitable for use with pressure injectors rated for a maximum of 330 psi when the access ports and stopcocks are removed and a direct connection is made with the proximal luer lock connector.

Deltaven Closed I.V. Catheter systems 26G are not suitable for the administration at high pressure.

Attribute	Subject Device – K171530 Deltaven Closed IV Catheter System	Predicate Device – K102520 BD Nexiva IV Closed Catheter System	Comparison
IV Catheter Type	Safety Closed IV Catheter system	Safety Closed IV Catheter system	Same
Intended use	Deltaven Closed I.V. Catheter systems are catheters for short-term (less than 30 days) peripheral venous access that allow the collection of blood samples and administration of fluids intravascularly.	The Nexiva intravascular catheter is inserted into a patient's vascular system for a short-term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravascularly.	Same
Single use	Yes	Yes	Same
Sharps injury prevention feature	Yes	Yes	Same

Attribute	Subject Device – K171530 Deltaven Closed IV Catheter System	Predicate Device – K102520 BD Nexiva IV Closed Catheter System	Comparison
Needle Material	Stainless Steel	Stainless Steel	Same
Needle Gauge Sizes	16 – 26 G	18 – 24 G	Different
Needle distal end configuration	Back cut configuration	Back cut configuration	Same
Sterilization Method	EO	EO	Same
Pressure Resistance	330 psi	300 psi	Different
Tubing proximal end configuration	Female 6 % Luer lock, in accordance with ISO 594-2	Female 6 % Luer lock, in accordance with ISO 594-2	Same
Catheter tube material	Polyurethane	Polyurethane (Vialon)	Different
Tubing Extension line dimension	26 – 18 G; ID 1.2 mm 16 G; ID 1.6 mm	For 24 - 22G ; ID 1.22mm 20 - 18G; ID 1.65mm	Different

Substantial Equivalence Discussion

The characteristics of the subject device, Delta Med Closed IV Catheter system, are compared with the selected predicate device cleared under K102520:

The indications for use statement and the intended use of the subject device are equivalent to the predicate device. The differences between the devices are:

1. Sharps injury prevention feature:
   The subject device and the predicate device both have integral safety features to help prevent needlestick injuries. The needlestick protection engages passively, without any specific action from the user apart from withdrawal of the needle, which engages the safety mechanism to cover the needle point. Even though differences exist between the methods employed for protecting the needle tip, the two devices are equivalent in this respect. Performance testing was provide to verify/validate the sharps injury prevention feature.

2. High pressure use:
   For the Nexiva range, gauge sizes from 22G to 18G are suitable for high pressure injection (300 psi), while the 24G model is excluded from high pressure usage. The subject device is suitable for high pressure usage from 24 G to 16 G, however, the 26G Deltaven device is excluded from high pressure use. Performance data has been provided to verify pressure injection up to 330 psi in these device configurations.

3. Configurations:
   The predicate device is available in four proximal end configurations, two with a single entry connections, and two with dual entry connections. In comparison, the subject device has five basic proximal end configurations. Each of these five configurations is also available in a 'fast flash' version, which is substantially equivalent to the 'InstaflashTM' rapid flow visualization system integral to the predicate device range. These differences in proximal connection types do not affect the intended use of the devices

4. Material:
   The predicate BD Nexiva catheters are made from a polyurethane material named Vialon whereas the subject Deltaven catheters are made from polyurethane named Pellethane®, which is the same material used for manufacture of the Neo Delta Self Safe Catheter, cleared under K121007.

5. Vent Plug:
   Both the predicate and the subject catheters are provided with vent plugs on their final connections (single and dual entry). The presence of the vent plug prevents blood leakages from the final connections and visualization chamber. Testing was performed to verify the performance of the vent plug. The predicate and subject devices are therefore substantially equivalent in this respect.

6. Needle point:
   The subject device and the reference device K121007 use stainless steel AISI 304 for the needles. The needle points are very similar and substantially equivalent between the predicate and the subject devices, as demonstrated photographically. Testing was performed to verify the performance and characteristics of the needle.

7. Extension Tubing:
   The predicate BD Nexiva and subject Deltaven catheter systems are both provided with extension lines, but the dimensions are different. Both use microbore tubing and for the 18G to 22G catheters, the subject Deltaven device has a 0.45 mm smaller internal diameter. This difference has an impact on the flow rates, with the subject device range generally being lower, although substantial equivalence between the two ranges is not compromised by this difference. In order to further demonstrate substantial equivalence, a tensile force of 15 N was applied for 15 seconds between the tube and the hub to samples of each device type, demonstrating that there was no breakage or separation.

8. Catheter/Needle gauge size:
   The predicate Nexiva range includes catheter/needle sizes between 24G and 18G, whereas the subject Deltaven range includes sizes from 26G to 16G. Performance testing was provided to verify use of the device at all gauge sizes.

Based on the above similarities and differences, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.

Bench/Performance/Non-Clinical Testing

The Deltaven Closed IV Catheter Systems meet the relevant technical requirements of the following standards:

- ISO 594-1:1986 - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2:1998 - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 10555-1:2013 - Intravascular catheters -- Sterile and single-use intravascular catheters -- Part 1: General requirements
- ISO 10555-5:2013 - Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters

- ISO 23908:2011 - Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 80369-7:2016 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

The Deltaven Closed IV Catheter Systems are supplied sterile for single use, sterilized with ethylene oxide (ETO) gas, and meet the biocompatibility requirements of the applicable standards in the ISO 10993 series. The following biocompatibility testing were completed: cytotoxicity, irritation, sensitization, acute systemic toxicity, material-mediated pyrogen, bacterial-mediated pyrogen, genotoxicity, sub-chronic toxicity, implantation, hemolysis, complement activation, in vivo thrombogenicity, and Limulus Amebocyte Lysate (LAL) testing.

The following testing was conducted in accordance with the applicable requirements of the above standards, to show safety and effectiveness as well as substantial equivalence to the predicate device:

- Radio-detectability (ISO 10555-1)
- Surface testing (ISO 9626, ISO 10555-1 and ISO 10555-5)
- Corrosion testing (ISO 9626 and ISO 10555-1)
- Peak tensile force (ISO 10555-1)
- Freedom from leakage under pressure (ISO 10555-1)
- Freedom from leakage during aspiration (ISO 10555-1)
- Gauging (ISO 594-2 and ISO 594-1)
- Liquid leakage (ISO 594-2, ISO 594-1 and ISO 80369-7)
- Air leakage during aspiration (ISO 594-2-ISO 594-1)
- Sub-atmospheric pressure air leakage (ISO 80369-7)
- Unscrewing torque (ISO 594-2, ISO 80369-7)
- Separation force (ISO 594-2, ISO 80369-7)
- Easy to assembly (ISO 594-2)
- Resistance of overriding (ISO 594-2, ISO 80369-7)
- Stress cracking (ISO 594-2, ISO 80369-7)
- Leakage by pressure decay (ISO 80369-7)
- Needle material (ISO 9626)
- Needle stiffness (ISO 9626)
- Resistance of tubing to breakage (ISO 9626)
- Catheter unit (ISO 10555-5)
- Strength union between needle hub and needle tube (ISO 10555-5)
- Safety Closed IV Catheter system activation test (ISO 23908)
- Challenging safety device test (ISO 23908)
- Vent fitting (ISO 10555-5)

Additional testing was performed to verify:

- Priming volume
- Clinical significant hydration
- Pressure resistance

In addition, a Simulated Clinical Use Test was carried out to verify/validate use of the sharps protection device in accordance with:

- FDA *"Guide for Industry and staff – Medical Devices with Sharp injury Prevention Features"*
- *ISO 23908:2011 "Sharps injury protection. Requirements and Test method. Sharp protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling"*.

In all testing, the pre-determined acceptance criteria were met.

Conclusion

The subject device does not raise new or different questions of safety and effectiveness and are supported by non-clinical testing. The Deltaven Closed IV Catheter Systems is substantially equivalent to the BD Nexiva Closed IV Catheter System cleared under K102520.