August 26, 2020

Delta Med S.p.A
% Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Roma, 00153
Italy

Re: K200373
Trade/Device Name: Deltaven Fast Flash Closed I.V. Catheter Systems
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: July 22, 2020
Received: July 27, 2020

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. 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,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*
K200373

Device Name
Deltaven Fast Flash Closed I.V. Catheter Systems

Indications for Use *(Describe)*
Deltaven Fast Flash 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 Fast Flash 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 Fast Flash 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 Fast Flash 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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K200373

510(K) SUMMARY

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Preparation Date: August 24, 2020

Trade Name: Deltaven Fast Flash 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

Predicate Device: K171530; Deltaven Closed I.V. Catheter Systems

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. Catheter systems cleared under K171530 included the following five versions:

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

To the existing five models are added two new models by means of this 510(k):

- Deltaven NLP Fast Flash
- Deltaven Y-DNL 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

This 'Fast Flash' range was previously cleared under K171530 with the generic name Deltaven XiV Max Fast Flash Closed I.V. Catheter systems, but the words 'XiV Max' have now been deleted from the model names.

Indications for Use:
Deltaven Fast Flash 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 Fast Flash 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 Fast Flash 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 Fast Flash Closed I.V. Catheter systems 26G are not suitable for the administration at high pressure.

Description of design changes:
This 510(k) addresses the following design changes to the Deltaven Fast Flash Closed I.V. Catheter systems range:

Detail design changes:

- Extension line closure system: original slide clamp replaced with a pinch clamp
- Catheter hub wings: knurls were replaced with grooves on the bottom of the wings
- 20G and 18G extension lines: increased internal and external diameter
- Safety housing/container: increased length and push tap on the surface
- Needle sheath: new hooking of the needle sheath onto white finger grip and wings
- Introduction of alternative materials
- Change on the final connector dimension as consequence of the extension line changed dimensions for 20G and 18G Catheters
- Change on the catheter hub dimension as consequence of the extension line changed dimensions for 20G and 18G Catheters
- Change in sterilization subcontractor

Predicate device comparison:

CHARACTERISTIC	SUBJECT DEVICE Deltaven Fast Flash Closed I.V. Catheter systems	PREDICATE DEVICE Deltaven Closed IV Catheter Fast Flash	EQUIVALENCE
Device name	Deltaven Fast Flash Closed I.V. Catheter systems: • Deltaven Fast Flash • Deltaven Y Fast Flash • Deltaven SC Fast Flash • Deltaven Y- NL Fast Flash • Deltaven SC-NL Fast Flash • Deltaven NPL Fast Flash • Deltaven Y-DNL Fast Flash	Deltaven Closed IV Catheter System: • 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	Two new models added plus design changes to all models, as listed above
Manufacturer	Tipromed Srl for Delta Med SpA, Italy	Tipromed Srl for Delta Med SpA, Italy	Same
510(k) reference	K200373	K171530	N/A
Regulation name	Intravascular catheter	Intravascular catheter	Same
IV Catheter type	Over the needle peripheral catheter	Over the needle peripheral catheter	Same
Regulation no	21 CFR 880.5200	21 CFR 880.5200	Same
Product Code	FOZ	FOZ	Same
Indications for use	Deltaven Fast Flash 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 Fast Flash 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 Fast Flash 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 Fast Flash Closed I.V. Catheter systems 26 gauge are not suitable for administration at high pressure.	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 26 gauge are not suitable for administration at high pressure.	Same
Sharps injury prevention feature	Yes	Yes	Same
Safety mechanism	Passive activation	Passive activation	Same

CHARACTERISTIC	SUBJECT DEVICE Deltaven Fast Flash Closed I.V. Catheter systems	PREDICATE DEVICE Deltaven Closed IV Catheter Fast Flash	EQUIVALENCE
Safety mechanism activation	After the device is inserted in the vein, the introducer needle can be completely withdrawn until safety device activation. The introducer needle engages with the safety finger that closes its arms and hides the needle point within itself. The needle point is completely encased within the safety device.	After the device is inserted in the vein, the introducer needle can be completely withdrawn until safety device activation. The introducer needle engages with the safety finger that closes its arms and hides the needle point within itself. The needle point is completely encased within the safety device.	Same
Sharps injury prevention features remains activated during disposal	Yes	Yes	Same
Mode of operation	Conventional venipuncture technique	Conventional venipuncture technique	Same
Insertion technique	1-handed or 2-handed	1-handed or 2-handed	Same
Tubing extension line dimension	For 26G up to 22G: ID 1.2mm, For 20G up to 16G: ID 1.6mm	For 26G up to 18G: ID 1.2mm, For 16G: ID 1.6mm	Different
Catheter tube material	Polyurethane	Polyurethane	Same
Radio-opaque catheter tubing?	Yes	Yes	Same
Needle material	Stainless steel	Stainless steel	Same
Needle distal end configuration	Back cut configuration	Back cut configuration	Same
Gauge sizes available	From 26G up to 16G	From 26G up to 16G	Same
Color-coded?	Yes, according to ISO 10555-5	Yes, according to ISO 10555-5	Same
Tubing proximal end configuration	Conforms to ISO 80369-7	Conforms to ISO 594-1, ISO 594-2, ISO 80369-7	Same
Material biocompatibility	Biocompatible per ISO 10993	Biocompatible per ISO 10993	Same
Single use?	Yes	Yes	Same
Supplied sterile?	Yes	Yes	Same
Sterilization method	EO	EO	Same
Catheter Force at break	Conforms to ISO 10555-1	Conforms to ISO 10555-1	Same
Cannula bonding strength	Conforms to ISO 10555-5	Conforms to ISO 10555-5	Same
Flow rate	Conforms to ISO 10555-1	Conforms to ISO 10555-1	Same
Power injection usage?	Yes	Yes	Same
Pressure resistance?	330 psi	330 psi	Same
Prescription use only?	Yes	Yes	Same

Substantial Equivalence Discussion
The only differences between the predicate and subject devices are those identified earlier in this Summary. Specific bench tests have been completed to ensure the new models and modified devices perform to specification.

In addition, new materials have been introduced to the device range, and finished, sterile devices with these new materials have been subjected to biocompatibility tests in accordance with the applicable parts of ISO 10993 for the appropriate nature of patient contact and duration of contact.

The Indications for Use statement for the Deltaven Fast Flash Closed I.V. Catheter systems is unchanged from the predicate, K171530.

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
Accelerated aging: For tests at end of shelf life, Items were exposed to 60 ºC for 19 weeks for an equivalent of 5 years real time shelf life, in accordance with ASTM F 1980:2007, 'Standard Guide for Accelerated Aging of Sterile Medical Device Packages'.

Functional Tests: Verification/validation tests were carried out on all material versions of the new designs. All tests were carried out on finished sample devices that had been subjected to a standard ethylene oxide sterilization cycle. The test protocols and acceptance criteria used were the same as those used in the predicate submission.

Bench Tests: The following tests have been carried out and the results demonstrate that the devices to meet the applicable technical requirements of the following FDA-recognized standards:

- ISO 10555-1:2013, 'Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements'
- ISO 10555-5:2013, 'Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters'
- ISO 80369-7:2016, 'Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications'
- 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'
- USP <788> Particulates test — evaluation of particulates 10 microns in size and greater according to USP <788> acceptance criteria

Sterility: The subject devices are sterilized by ethylene oxide to achieve a sterilization assurance level (SAL) of 10^{-6}. The sterilization process has been validated according to ISO 11135:2014, 'Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices', using the half cycle overkill approach. The sterile packaging is unchanged in materials or methods from the predicate device.

Pyrogenicity: Sample subject devices produced with the new materials were tested for bacterial endotoxins by means of the limulus amebocyte lysate (LAL) test and found to be within limits.

Biocompatibility: Biocompatibility tests have been carried out based on criteria defined in ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management process* and FDA guidance on Use of the international Standard ISO 10993-1 *"Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management"* (2016).

Biocompatibility tests have been carried out as follows on new, sterile, complete devices:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation or intracutaneous reactivity (ISO 10993-10:2010)
- Acute Systemic toxicity (ISO 10993-11:2006)
- Subacute/Subchronic Toxicity (ISO 10993-11:2006)
- Haemocompatibility (ISO 10993-4:2002 and Amend. 1 2006)
    - ASTM hemolysis Assay – Direct contact and extract method
    - Complement Activation Sc5b-9 Assay
    - Thromboresistance evaluation
- Genotoxicity (ISO 10993-3:2014)
    - Bacterial Mutagenicity Test (Ames Assay)
    - In Vitro Mouse Lymphoma
- ISO Material Mediated Rabbit Pyrogen (ISO 10993-11:2006)
- EO residuals (ISO 10993-7:2008)

FDA Guidance: In addition, the following FDA guidance documents were considered during verification and validation of the design changes described in this submission:

- Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters, March 16, 1995
- Guidance for Industry and FDA Staff - Medical Devices with Sharps Injury Prevention Features - August 9, 2005

Conclusion

The modified device does not raise new or different questions of safety and effectiveness and this conclusion is supported by non-clinical testing. Deltaven Fast Flash Closed I.V. Catheter systems as modified are substantially equivalent to the predicate catheter systems cleared under K171530.