DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 5, 2014

Delta Med Spa
C/O Mr. Roger Gray
VP, Quality and Regulatory
Donawa LifeScience Consulting Srl
Piazza Albania, N° 10
Rome, Italy 00153

Re: K140175
Trade/Device Name: Delta Fly F20µ Micro Bore Winged Safety Needles and Delta Fly Micro Bore Winged Safety Needles
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 3, 2014
Received: July 8, 2014

Dear Mr. 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.

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" (21CFR 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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)*
K140175

Device Name
Delta Fly F20µ Micro Bore Winged Safety Needles and Delta Fly Micro Bore Winged Safety Needles

Indications for Use *(Describe)*
The Delta Fly F20µ Micro Bore Winged Safety Needles and the Delta Fly Micro Bore Winged Safety Needles are intended for short term use to access the peripheral vascular system for intravenous administration of fluids using a syringe or other compatible / appropriate devices.

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)*

Digitally signed by Richard C. Chapman -S
Date: 2014.08.04 16:02:40 -04'00'

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K140175

510(k) Summary in accordance with 21 CFR 807.92(c)

Device name:	Delta Fly F20µ Micro Bore Winged Safety Needles and Delta Fly Micro Bore Winged Safety Needles
Type of 510 (k) submission:	Traditional
Date of Submission:	21 January 2014
Manufacturer:	Delta Med SPA Via Guido Rossa 20 I-46019 Viadana (Mantova) Italy
FDA Registration Number:	3006846316
510 (k) Owner:	Delta Med SPA Via Guido Rossa 20 I-46019 Viadana (Mantova) Italy
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510 (k) Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 03 757 85915 +39 03 757 85201 rgray@donawa.com
FDA Product Code:	FPA
FDA Regulation Number:	880.5440
FDA Classification Name:	Set, Administration, Intravascular
Classification panel:	General Hospital and Personal Use Devices
Common name:	Intravascular administration set or Winged safety needle
FDA Classification:	Class II

FDA identification: An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion filter, an I.V. set stopcock, fluid delivery tubing, connector between parts of set, a side tube with a cap to serve as injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Indications for use: The Delta Fly F20µ Micro Bore Winged Safety Needles and the Delta Fly Micro Bore Winged Safety Needles are intended for short term use to access the peripheral vascular system for intravenous administration of fluids using a syringe or other compatible / appropriate devices.

Device description:

The Delta Med Delta Fly Winged Safety Needles are available in four versions, as follows:

- Delta Fly F20µ Micro Bore Winged Safety Needle 25G x 35 cm
- Delta Fly F20µ Micro Bore Winged Safety Needle 23G x 35 cm
- Delta Fly Micro Bore Winged Safety Needle 25G x 35 cm
- Delta Fly Micro Bore Winged Safety Needle 23G x 35 cm

The devices consist of a stainless steel needle encased in a body of plastic material, attached to a micro bore tube, ending proximally with a female Luer lock fitting closed by a final male Luer lock cap. The female Luer lock fitting includes a 20µ woven mesh filter in the F20µ versions of the device. The devices are equipped with a passive needle stick safety system for covering the tip of the needle upon needle withdrawal, in order to protect the operator from accidental needle stick injury.

To help identification between the two types (with and without filter), the male Luer lock proximal end cap is colored white on the versions with the filter and is transparent on the versions without the filter. To identify the needle size of each version, the winged body of the devices are color-coded - blue for the 23G versions and orange for the 25G versions.

The distal end of the device is a stainless steel needle. The needle point has a triple bevel design. At the proximal end is a Luer lock fitting. Both device versions (with and without the mesh filter) have a final female connection in compliance with the requirements of ISO 594-2.

Delta Fly Micro Bore Winged Safety Needles are supplied for short term use only, sterile for single use, sterilized with ethylene oxide (EO) gas, and meet the biocompatibility requirements of ISO 10993-1:2009.

The Delta Fly devices meet the relevant technical requirements of the following standard:

- ISO 594-2:1998
- ISO 9626:1991 including Amendment 1
- ISO 23908:2011

Performance Data:

Tests carried out on the Delta Fly devices in accordance with the applicable requirements of the above standards include:

- Surface testing (ISO 9626)
- Corrosion testing (ISO 9626)
- Gauging (ISO 594-2)
- Liquid leakage (ISO 594-2)
- Air leakage during aspiration (ISO 594-2)
- Unscrewing torque (ISO 594-2)
- Separation force (ISO 594-2)
- Easy to assembly (ISO 594-2)
- Resistance of overriding (ISO 594-2)
- Stress cracking (ISO 594-2)
- Needle material (ISO 9626)
- Needle stiffness (ISO 96269)
- Resistance of tubing to breakage (ISO 96269)
- Safety winged needle activation (ISO 23908)
- Safety device test (ISO 23908)

Furthermore, to confirm substantial equivalence to the predicate devices, the following tests were performed:

- Tensile strength winged needle (15N x 15 seconds)
- Tensile strength between wings and tube
- Tensile strength between adapter and tube
- Flow rate determination
- Dead space volume
- Air leakage test

In addition a Simulated Clinical Usage test was carried out 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".*

Delta Med conducted the study at four different hospitals to allow a sufficient number of health care professional who routinely use Winged Needles to provide a meaningful feedback on the device design.

The following significant points were resulted:

- During the tests, 100% of the safety mechanism of the devices activated correctly
- No tests failures occurred.

- All the results obtained give a positive evaluation of the Winged Needle safety mechanism.

Safety Mechanism

The safety device for the Delta Fly Micro Bore Winged Safety Needles is a component formed by a cover permanently connected to a support element which is in contact with patient's skin.

During activation of the safety feature, the cover completely hides the needle in such a way that the needle is completely encapsulated in the internal concave section of the cover.

During withdrawal of the needle at the end of the treatment, the user, with one hand and limited pressure, pulls back the device tube while with the other hand slides and locks the safety feature into place over the needle.

Comparison with predicate devices:

The predicate device selected for comparison with the **Delta Fly F20µ Micro Bore Winged Safety Needle** is:

Predicate Device 1 (PD 1):	Surflo Winged Infusion Set with Filter and Needle Protection (Surshield)
510(k) Sponsor:	Terumo Europe NV
510(k) Number:	K070547
Clearance Date:	25 May 2007
FDA Product Code:	FPA
Classification Name:	Set, Administration, Intravascular
Regulation No:	880.5440

The predicate device selected for comparison with the **Delta Fly Micro Bore Winged Safety Needle** is:

Predicate Device 2 (PD 2):..... Surflo Winged Infusion Set with Needle Protection (Surshield)
510(k) Sponsor:..... Terumo Europe NV
510(k) Number:..... K100946
Clearance Date:..... 2 August 2010
FDA Product Code:..... FPA
Classification Name:..... Set, Administration, Intravascular
Regulation No: 880.5440

The only significant difference between the subject devices and the predicate devices is that each have a safety feature to help prevent needlestick injuries. Even though differences exist between the methods employed for protecting the needle tip, the subject and predicate devices are equivalent in this and all other respects.

Conclusion:

No other significant differences that could affect device safety or effectiveness exist between the subject devices and the predicate devices, therefore it is concluded that:

- The Delta Fly F20µ Micro Bore Winged Safety Needle is substantially equivalent to the predicate device Terumo Surflo Winged Infusion Set with Filter and Needle Protection (Surshield), which is already in interstate commerce within the USA;

  and

- The Delta Fly Micro Bore Winged Safety Needle is substantially equivalent to the predicate device Terumo Surflo Winged Infusion Set with Needle Protection (Surshield), which is already in interstate commerce within the USA.