DELTA MED
MEDICAL DEVICES

*Solutions for Health*

K121007

DEC 28 2012

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

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|---|---|
| **Device Name:** | Delta Med Neo Delta Self Safe T and Neo delta Self Safe 1 IV Catheters |
| **Type of 510(k) submission:** | Traditional |
| **Date of Submission:** | 12 March 2012 |
| **Manufacturer:** | Delta Med Srl<br>Via Guido Rossa 20<br>I-46019 Viadana (Mantova)<br>Italy |
| **FDA Registration Number:** | 3006846316 |
| **510(k) Owner:** | Delta Med Srl<br>Via Guido Rossa 20<br>I-46019 Viadana (Mantova)<br>Italy |
| **Contact Person:**<br>**Phone:**<br>**Fax:** | Dr Carla Martani Farinotti<br>+39 03 757 85915<br>+39 03 757 85201 |
| **510(k) Contact:** | Mr Roger Gray<br>VP Quality and Regulatory<br>Donawa Lifescience Consulting<br>Piazza Albania 10<br>00153 Rome<br>Italy |
| **Phone:**<br>**Fax:**<br>**Email:** | +39 06 578 2665<br>+30 06 574 3786<br>rgray@donawa.com |
| **FDA Product Code:** | FOZ |
| **FDA Regulation Number:** | 880.5200 |
| **FDA Classification Name:** | Intravascular Catheter |
| **Classification Panel:** | General Hospital and Personal Use Devices |
| **Common Name:** | Safety Intravascular Catheter |
| **FDA Classification:** | Class II |

**FDA Identification:** An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials.

**Indications for Use:** Neo Delta Self Safe Catheters are intravascular catheters intended for short term use for the intravenous administration of fluids.

**Device Description:**

The Delta Med Neo Delta Self Safe 'T' and Self Safe '1' IV Catheters are two ranges of color-coded, single-entry, polyurethane (PUR) IV catheters available in 'non-winged' (the 'T' version) and 'winged' (the '1' version) varieties, in sizes from 14 to 24 gauge. All versions include a passive safety mechanism to protect users from needlestick injuries together with three radiopaque lines to allow x-ray visualization.

The catheters meet the relevant technical requirements of the following standards:

- ISO 594-1:1986
- ISO 594-2:1998
- ISO 9626:1991 including Amendment 1
- ISO 10555-1:1995, including Amendments 1 and 2
- ISO 10555-5:1996 including Amendment 1 and Correction 1

The catheters are supplied sterile for single use, sterilized with ethylene oxide (ETO) gas, and meet the biocompatibility requirements of ISO 10993-1:2009.

**Performance Data:**

Tests carried out on the catheters in accordance with the applicable requirements of the above standards include:

- Surface testing (ISO 10555-1 and ISO 9626)
- Corrosion resistance (ISO 10555-1 and ISO 9626)
- Force at break (ISO 594-2)
- Gauging (ISO 594-1)
- Unscrewing torque (ISO 594-2)
- Ease of assembly (ISO 594-2)
- Resistance to overriding (ISO 594-2)
- Stress cracking (ISO 594-2)
- Radiopacity (ISO 10555-5)
- Catheter unit measurements (ISO 10555-5)
- Needle material (ISO 9626)
- Cleanliness (ISO 9626)

- Needle stiffness (ISO 9626)
- Needle resistance of tubing to breakage (ISO 9626)
- Needle bevel (ISO 10555-5)
- Needle hub and needle tube bonding strength (ISO 10555-5)
- Vent fitting requirements (ISO 10555-5)

In addition, a Simulated Clinical Usage Test was carried out in accordance with the FDA *'Guide for Industry and FDA Staff – Medical devices with Sharps Injury Prevention Features'*.

Delta Med conducted the study at four different hospitals, with test participants being recruited from different departments within each hospital to allow a sufficient number of health care professionals who routinely use IV catheters to provide meaningful feedback on the device design. The Evaluation Questionnaire was submitted to 20 health care professionals and a total quantity of 1,000 devices was used during the tests.

The following significant points were noted from review of the completed Evaluator Questionnaires:

- During the tests, 100 % of the safety mechanisms of the devices activated correctly.
- No test failures, as defined in Section 2.5 above, occurred.
- All the results obtained give a positive evaluation of Neo Delta Self Safe safety mechanism.

No design changes were made following completion of the simulated clinical use study, because the conclusions from the study were that the Neo Delta Self Safe safety mechanism works consistently well, with a confidence level of 99.5 % that the failure rate is no more than 0.5 %.

**Comparison with predicate devices:**

The predicate devices selected for comparison with the Neo Delta Self Safe IV Catheters are:

Predicate device 1 (PD 1): Smiths Medical Advantiv K072419

Predicate device 2 (PD 2): B. Braun Introcan Safety IV Catheter K982805

The subject device and the two predicate devices all have a safety feature system to prevent needlestick injuries that is am integral part of the device. 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.

Although the subject device and predicate devices all include passive safety features, the mechanisms of action are different. Neo Delta Self Safe Catheters have a safety feature that during usage encases the catheter needle tip in the safety feature to prevent accidental needlestick injury. The Advantiv device completely encases the needle point in a protective housing in a manner very similar to the Neo Delta Self Safe Catheters. In the Introcan Safety device design, the needle point is protected between the arms of two stainless steel safety fingers.

In all three device designs, the result is that the needle tip is prevented from exposure during withdrawal, manipulation and subsequent disposal. Even though there are differences in the method of capturing the needle tip, the three devices are equivalent in this respect.

No other significant differences that could affect safety or effectiveness exist between the subject device and the predicate devices.

**Conclusion:**

Based on the information contained within this submission, it is concluded that the subject device, Delta Med Neo Delta Self Safe IV Catheters types 'T' and '1', are substantially equivalent to the identified predicate devices that are already in interstate commerce within the USA.

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

December 28, 2012

Delta Med Srl
C/O Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome, Italy 00153

Re: K121007
Trade/Device Name: Neo Delta Self Safe Catheters
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 8, 2012
Received: November 13, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** K121007

**Device Name:** Neo Delta Self Safe Catheters

**Indications for Use:**
Neo Delta Self Safe Catheters are intravascular catheters intended for short term use for the intravenous administration of fluids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2012.12.27 15:08:34 -05'00'

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K121007