K132142

510(k) Summary

1. Submission Sponsor

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2. Submission Correspondent

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OCT 08 2013

3. Date Prepared

August 30, 2013

4. Device Identification

Trade/Proprietary Name:	neria™ soft 90 Infusion Set
Common/Usual Name:	Subcutaneous Infusion Set
Classification Name:	Intravascular administration set.
Classification Regulation:	21 CFR 880.5440, Set, Administration, Intravascular
Product Code:	FPA
Device Class:	Class II
Classification Panel:	General Hospital

5. Predicate Devices

K032854	Unomedical Inset™ Subcutaneous Infusion Sets (Formerly known as The Unomedical Monica Set)
K991759	Unomedical Quick-Set® Subcutaneous Infusion Sets (Formerly known as Maersk Medical Contour™ Infusion Set)

6. Device Description

The neria™ soft 90 subcutaneous infusion set is a new product designed by Unomedical based on the Unomedical Inset™ Subcutaneous Infusion Set and Unomedical Quick-Set® Subcutaneous Infusion Set.

The neria™ soft 90 is a 90 degree soft cannula infusion set with a standard luer-lock connection. The neria™ soft 90 subcutaneous infusion set consists of an introducer needle/insertion handle that inserts the soft cannula into the skin and is removed immediately after insertion, a cannula housing that rests upon the skin with adhesive tape, securing the soft cannula in place under the skin, tubing with disconnect option and a reservoir connector (standard luer lock) and disconnect cover for the tubing and cannula housing.

The proposed configurations are:

- Infusion Set - includes tubing and cannula
- Tubing Only
- Cannula only

7. Intended Use

The neria™ soft 90 infusion set is indicated for subcutaneous infusion of medication administered by an external pump.

8. Substantial Equivalence Discussion

The following table compares the neria™ soft 90 infusion set to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence. Please note that the two predicates included within their indications for use the following statement "The infusion set is neither intended nor indicated for use with blood or blood products" whereas the neria™ soft 90 product includes a very similar statement within the contraindications included in its instructions for use manual.

Table 5A – Comparison of Characteristics

Manufacturer	Unomedical	Unomedical	Unomedical
Trade Name	neria™ soft 90 infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Set)	Unomedical Quick-Set™ Subcutaneous Infusion Sets (Formerly known as Maersk Medical Contour™ Infusion Set)
510(k) Number	K132147	K032854	K991759
Product Code	FPA	FPA	FPA
Regulation Number	880.5440	880.5440	880.5440
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Intravascular Administration Set
Indications for Use	The neria™ soft 90 infusion set is indicated for subcutaneous infusion of medication administered by an external pump. *Please Note:* The IFU for this product includes the following contraindication: "The infusion set is neither intended nor indicated for intravenous infusion (I.V.) of medication, including blood and blood products"	The Unomedical Inset™ Subcutaneous Infusion Sets are intended for the subcutaneous infusion of medication, including insulin from an external pump. The infusion set is neither intended nor indicated for use with blood or blood products.	The Unomedical Quick-Set® Subcutaneous Infusion Sets are intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The infusion set is neither intended nor indicated for use with blood or blood products.
Material	Materials include Polypropylene, Stainless Steel, Polyethylene, Polyurethane, Silicone, Polycarbonate, Polytetrafluoroethylene, Meta Acrylonitrile Butadiene Styrene, Medical Grade Paper, UV-cured Glue, Colour Pigments	Materials include Polypropylene, Stainless Steel, Polyethylene, Polyurethane, Silicone, Polycarbonate, Polytetrafluoroethylene, Meta Acrylonitrile Butadiene Styrene, UV-cured Glue, Colour Pigments	Materials include Polypropylene, Stainless Steel, Polyethylene, Polyurethane, Silicone, Polycarbonate, Polytetrafluoroethylene, Meta Acrylonitrile Butadiene Styrene, Medical Grade Paper, UV-cured Glue, Colour Pigments
Sterile	Yes	Yes	Yes
Single-Use	Yes	Yes	Yes
Shelf Life	3 years	3 years	3 years
Complies with ISO 10993-1	Yes	Yes	Yes
Soft Cannula Length	6 and 9mm	6 and 9mm	6 and 9mm
Tubing Length	30, 60, and 110 cm	60 and 110 cm	60 and 110 cm
Angle of Insertion	90 degrees, perpendicular	90 degrees, perpendicular	90 degrees, perpendicular
Insertion Method	Insertion handle – manual insertion of	Insertion device, which enables the user not to	Insertion handle – manual insertion of

Manufacturer	Unomedical	Unomedical	Unomedical
Trade Name	neria™ soft 90 infusion set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Set)	Unomedical Quick-Set™ Subcutaneous Infusion Sets (Formerly known as Maersk Medical Contour™ Infusion Set)
	needle into tissue by user	place the soft cannula in the tissue manually	needle into tissue by user

9. Non-Clinical Performance Data

Testing performed to support substantial equivalence included:

- Functional tests:
  - Leak/Tightness
  - Flow (Occlusion)
  - Tensile test of introducer needle, tubing connections, soft cannula, adhesive tape, connector from cannula housing, connector needle

- Packaging tests
  - Dynamic Peel Test
  - Visual Peel Test
  - Print on Packaging and labelling

- Transportation Tests
  - Transportation tests general
  - Drop test

- Dimensional Tests
  - Distance soft cannula to set
  - Distance of introducer needle bevel to soft cannula
  - Length of tubes

- Biocompatibility Testing in accordance with ISO 10993-1
- EO/ECH residuals Testing
- Pyrogen/Endotoxin Testing
- Shelf life Testing and Sterilization Testing

As part of demonstrating safety and effectiveness of neria™ soft 90 infusion set and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Unomedical completed a number of tests. The neria™ soft 90 infusion set meets all the requirements for overall design, sterilization and biocompatibility. The neria™ soft 90 infusion set passed all testing stated above as shown by the acceptable results obtained.

The neria™ soft 90 infusion set complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Human Factors/Usability Testing

A Human Factors/Usability Engineering study was conducted to support the use of the neria™ soft 90 subcutaneous infusion set for its intended uses and the use environment.

The purpose of this evaluation was to demonstrate that users can perform critical tasks while using the product in a safe and effective manner. Unomedical has concluded that the neria™ soft 90 infusion sets can be used without a pattern of preventable use errors that would cause harm.

12. Statement of Substantial Equivalence

This device has the same overall intended use "are intended for the subcutaneous infusion of medication" as that of the predicates. The device incorporates features from each of the predicates listed which are also manufactured by this submission sponsor. Therefore by definition, this device, neria™ soft 90 infusion set, is substantially equivalent to the referenced predicate devices as the device has the same intended use and the same technological characteristics as the previously cleared predicate devices.

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

October 8, 2013

Unomedical A/S
C/O Ms. Deirdre Barrow
Senior Regulatory Consultant
Emergo Group
Unit B9, Taylors Court Parkgate
Rotherham, South Yorkshire
United Kingdom S62 6NU

Re: K132142
Trade/Device Name: neria™ soft 90 Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 10, 2013
Received: July 11, 2013

Dear Ms. Barrow:

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. Burner -S

Kwame Ulmer M.S.
Acting Division 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 Statement

510(k) Number (if known): K132142

Device Name: neria™ soft 90 Infusion Set

Indications for Use:

The neria™ soft 90 infusion set is indicated for subcutaneous infusion of medication administered by an external pump.

Prescription Use	AND/OR	Over-The-Counter Use _____
X		(21 CFR 801 Subpart C)
(Part 21 CFR 801 Subpart D)		

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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: 2013.10.07 13:25:06 -04'00'