December 13, 2019

Unomedical a/s
% Deirdre Barrow
Senior Consultant, Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K192647
Trade/Device Name: neria™ guard Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: September 23, 2019
Received: September 24, 2019

Dear Deirdre 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. 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 Geeta Pamidimukkala
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192647

Device Name
neria™ guard infusion set

Indications for Use *(Describe)*
The neria™ guard infusion set is indicated for subcutaneous infusion of medication administered by an external pump.

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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510(k) Summary

K192647

1. **Submission Sponsor**

   Unomedical a/s

   Aaholmvej 1-3, Osted

   DK-4320 Lejre,

   Denmark

   Contact: Mette Henningsen

   Title: Regulatory Affairs Specialist

2. **Submission Correspondent**

   Emergo Global Consulting, LLC

   2500 Bee Cave Road

   Building 1, Suite 300

   Austin, TX 78746

   Office Phone: (512) 327.9997

   Contact: Deirdre Barrow

   Title: Senior Consultant, RA

3. **Date Prepared**

   Dec-11-2019

4. **Device Identification**

   Trade/Proprietary Name: neria™ guard Infusion Set

   Common/Usual Name: Set, Administration, Intravascular

Classification Name: Intravascular administration set

Regulation Number: 880.5440

Product Code: FPA, Intravascular administration set

Device Class: Class II

Classification Panel: General Hospital

5. Legally Marketed Predicate Device(s)

Table 5A: Legally Marketed Predicate Device

Device Name	510(k) No.	Product Code	Classification Regulation	Classification Name	Sponsor
Unomedical Inset™ Subcutaneous Infusion Set (formerly known as the Unomedical Monica Infusion Set)	K032854	FPA	880.5440	Intravascular administration set	Unomedical

6. Indication for Use Statement

The neria™ guard Infusion Set is indicated for subcutaneous infusion of medication administered by an external pump.

7. Device Description

The neria™ guard Infusion Set manufactured by Unomedical is a sterile, non-pyrogenic, single use subcutaneous infusion set which includes a 90–degree soft cannula. It is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. The product is indicated for subcutaneous infusion of medication.

The insertion needle and soft cannula of the neria™ guard Infusion Set are hidden from the user before, during and after insertion of the soft cannula. This feature helps prevents needle stick injuries as the device does not require loading with the needle by the user, the needle is then automatically retracted after use.

8. Substantial Equivalence Discussion

The following table compares the neria™ guard Infusion Set to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

It should be noted that the cannula from the subject device and the predicate are identical (same materials from the same suppliers, same manufacturing process, same sterilization, same intended use). Differences between the subject device and predicate device include difference in the insertion method, needle retraction mechanism, additional available lengths, and material differences.

Table 5B – Comparison of Characteristics

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
510(k) Number	K192647	K032854	N/A
Product Code	FPA	FPA	Same
Regulation Number	880.5440	880.5440	Same
Regulation Name	Intravascular Administration Set	Intravascular Administration Set	Same
Indications for Use	The neria™ guard Infusion Set is indicated for subcutaneous infusion of medication administered by an external pump.	The Unomedical Inset™ Subcutaneous Infusion Sets are indicated for the subcutaneous infusion of medication from an external pump.	Similar- Difference in the name of the subject device. Does not impact safety or effectiveness
Mechanism of Action	The neria™ guard Infusion Set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	The Unomedical Inset™ Subcutaneous Infusion Set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	Same
Technology Overview	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle.	**Serter:** • Subcutaneous insertion of soft cannula by introducer needle situated inside soft cannula at a 90° insertion angle.	**Serter:** • Same angle of insertion and use of introducer needle and cannula

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	• insertion of soft cannula: 2 user steps for insertion: remove protective cap for base and press release button	• insertion of soft cannula: 3 manual user steps for insertion: loading, inserting and retraction.	• Both devices use an insertion device to insert the soft cannula, the proposed device has an insertion mechanism preloaded and ready for insertion by simply pressing the activation button after removing the safeguard. This technical difference is not clinically significant as while this additional safety feature does have a minor impact upon the method of operation of the device it does not introduce any new questions of safety or effectiveness.
	• The Base Set in neria™ guard Infusion Set is made of two components, the Fluid Part and the Base Part	• The Base Set used in Unomedical inset™ is moulded as one	• The fluid part of the neria™ guard Infusion Set assembly is inserted into the base assembly (on body). This step is not required for the Unomedical inset™ Infusion Set. This technical difference is not clinically significant as the additional required step for the proposed device does not significantly impact the method of

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	• The neria™ guard Infusion Set is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. The newly developed mechanism allows the needle to be hidden from the user and/or caregiver before and after insertion.	• The Unomedical Inset™ Subcutaneous Infusion Set does not have a mechanism for automatic needle retraction and the needle is visible to the user.	• The insertion needle and soft cannula of neria™ guard Infusion Set are hidden from the user before, during and after insertion of the soft cannula. This feature helps prevent needle stick injuries. This technical difference does not introduce any new questions regarding safety and effectiveness of the device. The additional safety feature does not impact the method of operation of the device.
	Administration Set: The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in to the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The indwelling catheter is introduced into the subcutaneous	**Administration Set:** The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in to the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The indwelling catheter is introduced into the subcutaneous	Same technology used in both devices for the administration set. It should be noted that the cannula from the subject device and the predicate are identical (same materials from the same suppliers, same manufacturing process, same sterilization, same intended use).

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	tissue by a removable 27 gauge introducer needle (cannula) made of AISI 304 stainless steel.	tissue by a removable 27 gauge introducer needle (cannula) made of AISI 304 stainless steel.	
Anatomical Location	Standard recommended sites for subcutaneous infusion of medication i.e. subcutaneous sites are selected based on the presence of adequate adipose tissue. The choice of insertion site depends on treatment and patient specific factors as recommended by HCP. Preference is given to sites that do not affect the patient's mobility, the insertion site has to be free of skin irritation and inflammation such as redness, scar tissue and bleeding. Site selection: the abdomen, in a roughly semicircular area around and below the umbilicus is preferred as an application site. Other insertion sites include the upper leg, upper buttocks, hips, upper arms and lower back and occasionally the chest when others sites have edema. The area to place the infusion set is	Standard recommended sites for subcutaneous infusion of medication i.e. subcutaneous sites are selected based on the presence of adequate adipose tissue. The choice of insertion site depends on treatment and patient specific factors as recommended by HCP. Preference is given to sites that do not affect the patient's mobility, the insertion site has to be free of skin irritation and inflammation such as redness, scar tissue and bleeding. Site selection: the abdomen, in a roughly semicircular area around and below the umbilicus is preferred as an application site. Other insertion sites include the upper leg, upper buttocks, hips, upper arms and lower back and occasionally the chest when others sites have edema. The area to place the infusion set is	Same

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
	particularly important in patients with many years use, since the overuse of skin sites has an influence on absorption variability.	particularly important in patients with many years use, since the overuse of skin sites has an influence on absorption variability.	
Material	Materials include: Polypropylene, polyoxymethylene, stainless steel, polytetraflouroethylene, nonwoven polyester/polyacrylate, polyethylene, silicone, Methyl Methacrylate Acrylonitrile Butadiene Styrene(MABS), Terlux 2802 HD, transp., medical grade paper, polycarbonate	Materials include: Polypropylene, Stainless Steel, Polyethylene, Polyurethane, Silicone, Polycarbonate, Polytetrafluoroethylene, Methyl Methacrylate Acrylonitrile Butadiene Styrene(MABS), Terlux 2802 HD, transp., Medical Grade Paper, UV-cured Glue, Colour Pigments	Differences in material were evaluated with the appropriate biocompatibility testing per ISO 10993-1.
Sterile	Yes – EO – SAL 10^{-6}	Yes – EO – SAL 10^{-6}	Same
Single-Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Complies with ISO 10993-1	Yes	Yes	Same
Soft Cannula Length	6 and 9mm	6 and 9mm	Same
Tubing: **ID** **OD**	0.385 mm, 1.50 mm	0.385 mm, 1.50 mm	Same
Soft Cannula OD	0.68 mm	0.68 mm	Same

Manufacturer	Unomedical	Unomedical	Device Comparison
Trade Name	neria™ guard Infusion Set	Unomedical Inset™ Subcutaneous Infusion Sets (formerly known as The Unomedical Monica Infusion Set)	
Needle Gauge	27 gauge	27 gauge	Same
Tubing Length	12 cm, 30 cm, 60 cm, 80 cm and 110 cm	60 and 110 cm	Additional tubing lengths of 12, 30 and 80 cm have been made available for the proposed device. Does not impact safety or effectiveness.
Angle of Insertion	90 degrees, perpendicular	90 degrees, perpendicular	Same
Insertion Method	Pre–loaded insertion device with automatic needle retraction. The insertion needle and soft cannula are hidden from the user before, during and after insertion of the soft cannula.	Insertion device, which enables the user not to place the soft cannula in the tissue manually	Similar in that both devices allow for the patient to not have to insert the device in the tissue manually – the proposed device includes an additional mechanism so that the patient does not need to see the needle or cannula at any stage of the process and has an automatic needle retraction to help ensure needle safety
Time of Use	Up to 72 hours	Up to 72 hours	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of neria™ guard Infusion Set and in showing substantial equivalence to the predicate device, Unomedical completed a number of non-clinical performance tests. The neria™ guard Infusion Set meets all the requirements for overall design, sterilization, biocompatibility and usability confirming that the design output meets the design inputs and specifications for the device.

The neria™ guard Infusion Set has met the requirements for testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- **Sterilization Testing**

  The sterility of the neria™ guard Infusion Set is assured by using a validated sterilization method qualified in accordance with ISO 11135:2014.

- **Biocompatibility testing**

  The biological safety of the neria™ guard Infusion Set was demonstrated by testing in accordance with ISO 10993-1:2009 and guidance document entitled *Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing within a Risk Management Process"* dated 16 June 2016.

  The battery of testing included the following tests:

  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity/Irritation
  - Acute and 14-day Systemic toxicity
  - Material Mediated Pyrogenicity
  - Hemolysis
  - Particulate Testing
  - Chemical Characterization
  - Genotoxicity (AMES and MLA)

- **Shelf Life Determination**

  A maximum shelf life of 3 years was determined based on an assessment of the seal integrity of the sterile barrier packaging and functional testing of the device in accordance with ASTM F1980:2011.

- **Functional Testing**

Placement Introducer Needle before and after activation
Tensile Test Base-Connector
Functional Test Adhesive Liner
Contents in Blister Package
Functional Test Serter
Tensile Test Needle Hub
Tensile Test Soft Cannula
Tensile Test Base- Adhesive Patch
Peel Test Packaging
Disassemble fluid part from base
Disassemble base from cylinder
Serter Activation Force
Leak Test
Flow Test
Distance Introducer Needle bevel to Soft Cannula tip
Distance Soft Cannula tip to bottom fluid part
Visual Test of IFU, Blister Lid and Inner and Outer box label
Disassemble Cylinder from Cover
Drug Compatibility Testing
Tensile Strength
Packaging and Labelling tests

Standards used:

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

ASTM F1980:2011; Standard Guide or Accelerated Aging of Sterile Barrier Systems for Medical Devices

ISO 11607-1:2009; Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 10993-1:2009; Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

ISO 14971:2012; Medical devices. Application of risk management to medical devices

ISO 10993-11:2006; Biological evaluation of medical devices -- Part 11: Tests for systemic cytotoxicity

ISO 11607-2:2006; Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

ASTM D4169-16; Standard Practice for Performance Testing of Shipping Containers and Systems

10. Conclusion

The neria™ guard Infusion Set, as designed and manufactured, is determined to be substantially equivalent to the predicate device.