DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 11, 2017

ConceptoMed AS
Marit Martinsen
QA Manager
Hattvikveien 2
Ballstad, N-8373
NORWAY

Re: K162057
Trade/Device Name: ConceptoMed Luer-Jack Slip 10ml
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: October 8, 2016
Received: October 14, 2016

Dear Marit Martinsen:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tina Kiang, Ph.D.
Acting 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)*
K162057

Device Name
ConceptoMed Luer-Jack Slip 10ml

Indications for Use *(Describe)*
Indications and Intended Use:
The ConceptoMed Luer-Jack device is a sterile syringe without needle intended for single use by health care professionals for general purpose aspiration or injection of fluids immediately after filling. The device is intended to be used only in combination with female 6% Luer slip connectors.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ConceptoMed

510(k) SUMMARY

Summary of Safety and Effectiveness
For Luer-Jack Slip

In accordance with 21 CFR 807.92, the following information constitutes the ConceptoMed AS summary for the Luer-Jack Slip 10ml.

SUBMITTER'S NAME:	ConceptoMed AS
ADDRESS:	Hattvikveien 2 8373 Ballstad Norway
CONTACT PERSON:	Marit Martinsen, Director QA & Regulatory, ConceptoMed AS
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E-MAIL	marit.martinsen@conceptomed.no
DATE OF SUBMISSION:	January 4, 2017

1. Subject Device

Trade Name:	ConceptoMed Luer-Jack Slip 10ml
Common Name:	Luer-Jack Slip 10ml
Regulation Number:	21 CFR §880.5860
Regulation Name:	Piston syringe
Regulatory Class:	II
Product Code:	FMF
Classification Panel:	General Hospital

2. Predicate Device

Trade Name:	BD Single use, Hypodermic Syringe
510(k) Reference:	K110771
Common Name:	BD Single use, Hypodermic Syringe
Regulation Number:	21 CFR §880.5860
Regulation Name:	Piston syringe
Regulatory Class:	II
Product Code:	FMF
Classification Panel:	General Hospital

3. Description of the Device

The Luer-Jack Slip 10ml is a five-piece, single use syringe without needle, with a 6% (Luer) male slip connector. The device includes a three-piece syringe with a plastic barrel with graduated scale, a stopper and a plastic plunger rod. Upon the barrel is a single-handed needle hub release system in two pieces. The Luer-Jack is used as a general syringe except when disconnecting from a compatible female 6% (Luer) connector.

For disconnection the hub release system mounted upon the barrel is used. The Luer-Jack will be delivered sterile (sterilized by irradiation) in a hard blister pack (the Steri-Tilt™).

4. Indications for use

The ConceptoMed AS Luer-Jack device is a sterile syringe without needle intended for single use by health care professionals for general purpose aspiration or injection of fluids immediately after filling. The device is intended to be used only in combination with female 6% Luer slip connectors.

5. Technological characteristics, comparison to predicate device.

The subject is a sterile syringe without needle intended for single use by health care professionals for general purpose aspiration or injection of fluids immediately after filling. The subject is intended to be used only in combination with female 6% Luer slip connectors.
The Device is claimed to be Substantially Equivalent (SE) to the device *BD Single Use, Hypodermic Syringe*, manufactured by *Becton, Dickinson and Company* (Predicate Device).

The syringe used in the Luer-Jack is manufactured under the same conditions as the predicate device (K110771) apart from packaging and sterilization as the syringe is delivered in bulk to ConceptoMed.

Based on the intended use, the Luer-Jack Slip 10 ml is considered Substantially Equivalent to the predicate device, given that:

a) The Luer-Jack Slip 10 ml has the same similar intended use as the predicate device, the only minor difference is the addition of the Luer-Jack component designed to aid the clinician with one-handed removal.
b) The Luer-Jack Slip 10 ml barrel and plunger rod (including rubber piston) use the identical design and identical materials as the predicate device.
c) The Luer-Jack Slip 10 ml and the predicate device meet the requirements for manual use as defined by ISO 7886-1.
d) The Luer-Jack Slip 10 ml and the predicate device component materials comply with ISO 10993-1 as applicable to the intended use of the device.
e) The Luer-Jack Slip 10 ml and the predicate device are sterilized to an SAL of 10^{-6} via an E-Beam irradiation process.

But differs when it comes to;

- *be of similar design;*
  The Luer-Jack Slip 10 ml has an integrated hub release system.
- *be of similar material;*
  The Luer-Jack Slip 10ml integrated hub release system is manufactured from biocompatible MABS-polymer.
- *have similar principles of operation*
  The subject and the predicate device are both operated as general syringes. The subject may be disconnected from female hubs with a traditional two-handed operation. However, the integrated hub release system may also be used for a one-handed disconnection.

6. Summary of performance testing.

Design Verification tests were performed based on the risk analysis. The results of these tests demonstrate that the Luer-Jack Slip 10ml performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

Design Verification testing included the following performance testing with "PASS" on all criteria:

Performance Characteristic	*Acceptance Criteria*
System use	
Sterilization	Valid sterilization documentation
Manufacturing and assembly in cleanroom	Cleanroom for ISO-class 8
Safety functions	
Connector compatibility	1. Designed for Luer connections 2. Designed with connectors with 6% female Luer fittings
Catch mechanism	Functional catch mechanism
Usability	
One-hand handling and usability of blister	**A** Use of gloves during handling **B** Use in combination with a PVC
Regulatory	
Standard for syringes	Conformance to EN ISO 7886-1:1993
Biocompatibility	Conformance to EN ISO 10993-1:2009/AC:2010
Packaging safe for sterilization	1) Existence of Packaging and labelling specification. Compliance with Packforsk Std-40-101 2001 Transport tests (including air transportation) 2) Packaging material intended for irradiation sterilization
Lifetime and reliability	
Shelf life	Shelf life of 4 years
Mechanical requirements	
Drop test	No damage of the packages, and full functionality of device
Press fit test	Withstand a pulling force of 20 N
Mechanical strength	a) Full function of the Lever after 15 full cycles b) A mechanical report shall conclude sufficient mechanical strength
No interference when connected	Functionality after 70N push force
Surface contact	Ability to use with a PVC
Functionality	
Transparency of Lever and Collar	Visual control of graduation lines

The Device will be marketed as a piston syringe with one-handed disconnection option only.

7. Conclusion

The Luer-Jack has been verified to meet the established performance criteria above. The predicate device is a well known and well documented device, the Luer-Jack performs comparably to the predicate device that is currently marketed for the same intended use.

Based on the clinical performance as well as biocompatibility characteristics, the Luer-Jack was found substantially equivalent to the predicate device.