DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 8, 2017

ConceptoMed AS
Marit Martinsen
Director QA & Regulatory
Hattvikveien 2
Ballstad N-8373
NORWAY

Re: K171805
Trade/Device Name: Luer-Jack Slip 3 ml, Luer-Jack Slip 5 ml, Luer-Jack Slip 20 ml, Luer-Jack Lock 10 ml
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 3, 2017
Received: August 10, 2017

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" (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 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,

Tara A. Ryan -S

for
Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*

K171805

Device Name
LuerJack Slip 3 ml, 5 ml, 20 ml
LuerJack Lock 10 ml

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 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.

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510(K) Summary K171805

SUBMITTER'S NAME: ConceptoMed AS

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DATE OF SUBMISSION: July 31, 2017

1. Subject Device

Trade Name:	Subject Device 1 – LuerJack Slip 3 ml Subject Device 2 – LuerJack Slip 5 ml Subject Device 3 – LuerJack Slip 20 ml Subject Device 4 – LuerJack Lock 10 ml
Common Name:	LuerJack Slip/ LuerJack Lock
Regulation Number:	21 CFR §880.5860
Regulation Name:	Piston syringe
Regulatory Class:	II
Product Code:	FMF
Classification Panel:	General Hospital

2. Predicate Devices

Predicate Device

Trade Name:	ConceptoMed Luer-Jack Slip 10 ml
510(k) Reference:	K162057
Common Name:	Luer-Jack Slip 10 ml
Regulation Number:	21 CFR §880.5860
Regulation Name:	Piston syringe
Regulatory Class:	II
Product Code:	FMF
Classification Panel:	General Hospital

Reference 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 LuerJack is a five-piece, single use syringe without needle, with a male 6% (Luer) connector in 3 ml, 5 ml, 10ml, 20 ml Luer Slip and 10 ml Luer Lock syringe sizes. The device includes a three-piece slip syringe (the Reference Device) with a barrel with graduated volume scale, a stopper and a plunger rod. Onto the barrel is a single-handed hub release system in two pieces monunted. The hub release system provides a single-handed connector release system for all Subject Devices and the additional locking function for the LuerJack Lock syringe.
The LuerJack is used as a general syringe except when disconnecting from a compatible female 6% (Luer) connector. The LuerJack is delivered sterile (sterilized by irradiation) in a syringe only configuration. The LuerJack is used as a general syringe except when disconnecting from a compatible female 6% (Luer) connector. For disconnection of an attached connector, the hub release system mounted onto the barrel is used.

4. Indications for use

The LuerJack device is a sterile syringe without needle intended for single use by healthcare 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 connectors.

5. Technological characteristics; comparison to predicate device

The Subject Devices are equivalent to the Predicate Device (K162057) in intended use and performance characteristics.
The Subject Devices are assembled and sterilized under the same conditions as the Predicate Device.
Disconnection of attached devices is identical for both the Subject Devices and the Predicate Device.
Subject Device 1, 2 and 3 are equivalent to the Predicate Device in materials and design.
Subject Device 4 (LuerJack Lock 10 ml) is different from the Predicate in terms of materials. The difference is the added Petrolatum between the collar and lever.
Subject Device 4 (LuerJack Lock 10 ml) is different from the Predicate in terms of design. The difference in design is the added 205° protrusion with an integrated

locking mechanism.

Element of Comparison		Subject Device	Primary Predicate Device (PD1)
Indications for Use/ Intended Use		The LuerJack is a sterile syringe without needle intended for single use by healthcare 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 connectors.	The LuerJack is a sterile syringe without needle intended for single use by healthcare 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.
Barrel size		3 ml, 5 ml, 20 ml slip – identical to reference device K110771 10 ml – identical to predicate device K162057	10 ml slip – identical to subject device
Syringe materials	Barrel	Polypropylene	Polypropylene
	Barrel Lubricant	Silicone	Silicone
	Plunger Rod	Polypropylene	Polypropylene
	Stopper	Rubber	Rubber
	Stopper Lubricant	Silicone	Silicone
	Only Subject Device 4 – Outside Barrel Lubricant	Petrolatum (Vaseline)	N/A
Sterilization Method		E-Beam	E-Beam
SAL		10^{-6}	10^{-6}

Reference device K110771 used for comparison to the different syringe barrel sizes 3 ml, 5 ml, 20 ml slip – which are identical to the additional sizes of the subject device.

6. Summary of performance testing.

Design Verification tests were performed based on the risk analysis. The results of these tests demonstrate that the Subject Device performed in an equivalent manner to the Predicate Devices 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	
Catch mechanism	Functional catch mechanism
Connector compatibility	Designed to fit female 6% Luer connectors
Functional testing	
Sustaining Force (ISO 7886-1:1997 - Annex G)	Per ISO 7886-1:1997
Break-Out Force (ISO 7886-1:1997 - Annex G)	Per ISO 7886-1:1997
Pump Sticktion/ Force (ISO 7886-2:1996 - Annex C)	Per ISO 7886-2:1997
Stopper Seal (ISO 7886-1:1997 - Annex D)	Per ISO 7886-1:1997
Autoclavability (ISO 7886-1:1997 - Annex D)	Per ISO 7886-1:1997
Chemical testing (Extractables)	
Zinc	Per ISO 7886-1:1997
Lead, Tin, Iron	
Cadmium	Per ISO 7886-1:1997
pH shift	Per ISO 7886-1:1997
Biocompatibility	
Cytotoxicity	Conformance to EN ISO 10993-5:2009
Sensitization	Conformance to EN ISO 10993-10:2010
Irritation or Intra cutaneous reactivity	Conformance to EN ISO 10993-10:2010
Acute Systemic Toxicity	Conformance to EN ISO 10993-11:2009
Material-Mediated Pyrogenicity	Conformance to EN ISO 10993-11:2009
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	Valid shelf life on blister and device
Mechanical requirements	
Drop test	No damage of the packages, and full

	functionality of device
Mechanical strength	a) Full function of the Lever after 15 full cycles b) A mechanical report shall conclude sufficient mechanical strength
Initial force level before Lever press down	Initial force of 2N needed before click and release activation
Complete functional performance requirements from ISO 80369-7	Leakage, separation force, unscrewing and overriding torque

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

7. Substantial Equivalence

The LuerJack Slip 3 ml, 5 ml and 20 ml and the LuerJack Lock 10 ml are equivalent to that of the Predicate ConceptoMed Luer-Jack Slip 10 ml in intended use, principles of operation, technology, materials and performance characteristics.

8. Conclusion

The LuerJack Slip 3 ml, 5 ml and 20 ml and the LuerJack Lock 10 ml has been verified to meet the established performance criteria above. The LuerJack Slip 3 ml, 5 ml and 20 ml and the LuerJack Lock 10 ml performs as intended and comparably to the legally marketed Predicate Device.