



Food and Drug Administration
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April 12, 2016

Ypsomed AG
% Lee Leichter
President
P/L Biomedical
10882 Stonington Avenue
Fort Myers, Florida 33913

Re: K150921

Trade/Device Name: Orbit®micro Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: March 8, 2016
Received: March 11, 2016

Dear Mr. Lee Leichter:

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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use

510(k) Number (if known)
K150921

Device Name
Orbit®micro Infusion Set

Indications for Use (Describe)

Orbit®micro Infusion Sets are intended for the subcutaneous delivery of fluids and medication, such as insulin, from an external infusion 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY for K150921

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Date Prepared:

March 08, 2016

1. Trade/Proprietary Name: Orbit[®] micro Infusion Set
2. Common/Usual Name: Subcutaneous Infusion Set
3. Classification Name: Intravascular Administration Set

Classification:

Class: II
Panel: 80
Product Code: FPA
Regulation: 21 CFR 880.5440

4. Predicate Device: K130468 Orbit Infusion Set
5. Purpose of Submission:
To market a product line of subject devices, designed with stainless steel cannulas as an alternative to the predicate devices designed with soft catheters and stainless steel insertion needles.

6. Device Description

All Orbit[®] micro Infusion Sets are used for the subcutaneous delivery of fluids and medication from an external infusion pump. All Orbit[®] micro Infusion sets are comprised of tubing that is connected on one end to the medication reservoir of the infusion pump using a luer lock connection and on the other end to the patient, attached to the skin by an adhesive base, anchoring a catheter that is inserted into the subcutaneous tissue. All Orbit[®] micro Infusion sets have a patented design feature which allows the tubing to freely rotate 360° at the adhesive attachment and to disconnect the tubing set from the infusion base. The subject devices use a stainless steel indwelling cannula instead of the Teflon cannula in the predicate devices.

7. Intended Use:

The intended use of the subject devices remains the same as the predicate devices (K130468):

Orbit[®] micro Infusion Sets are intended for the subcutaneous delivery of fluids and medication, such as insulin, from an external infusion pump.

8. Technological Characteristics:

The technological characteristics of the subject devices are the same as for the predicate devices (K130468). There are some changes in components, materials and dimensions. All significant differences are described below.

Otherwise the Subject devices have the same indications for use, intended use and the same design including connectors, tubing lengths and diameters, materials, dimensions and operating principles as the currently marketed predicate devices.

Characteristic	Predicate device	Subject device	Comments
Dimensions			
Cannula Diameter	Soft Cannula: ID 0.44mm OD 0.76mm Introducer Needle: ID 0.20 mm OD 0.41 (27G)	Stainless steel cannula (31G): ID 0.11 mm OD 0.25 mm Stainless steel cannula (27G): ID 0.24 mm OD 0.41 mm	Different dimensions
Cannula Length	6mm, 9mm	5.5mm, 8mm, 8.5mm	Different dimensions
Tubing Length	30cm (12 inch) - 105cm (42 inch)	30cm (12 inch) - 105cm (42 inch)	Identical
Tubing Diameter	0.020 x 0.062 inch (0.51 x 1.57mm)	0.020 x 0.062 inch (0.51 x 1.57mm)	Identical
Material of components			
Female Luer	PVC	PVC	Identical
Tubing	PVC – outer layer PE Polyethylene (LDPE) - inner layer co-extruded	PVC – outer layer LDPE - inner layer co-extruded	Identical
Cap, Tubing	MABS	MABS	Identical
Septum	Polyisoprene	Polyisoprene	Identical
Adhesive Tape	Nonwoven Medical Tape	Nonwoven Medical Tape	Identical
Base	PC	PC	Identical
Cap, Needle	MABS	MABS	Identical
Lubrication	Silicon	Silicon	Identical
Needle Protector	HDPE/LDPE	HDPE/LDPE	Identical
Tape	Cohesive Tape	Cohesive Tape	Identical

Metal anchor (Eyelet)	Stainless Steel	N/A	N/A
Introducer Needle	Stainless Steel	N/A	N/A
Blue needle cover	HDPE/LDPE	N/A	N/A
Characteristic	Predicate device	Subject device	Comments
Catheter / Cannula	FEP catheter	Stainless Steel cannula	Different material for the cannula, but the same stainless steel as for the introducer needle of the subject device
UV Glue bond	Adhesive	Adhesive	Same type of adhesive (acrylic urethane adhesive, UV-cured), different viscosity
Packaging Material			
Primary Packaging	Blister sealed with Tyvek lid	Blister sealed with Tyvek lid	Identical
Sterilization			
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical

9. Performance Data

Ypsomed has performed the relevant assessments specified in the following international and internal standards and protocols and confirmed compliance of the modified devices and equivalence to the predicate devices. The Orbit[®] micro Infusion Sets have met the requirements of the relevant sections of the following standards:

Test	Specification	Results
Material strength of steel cannula	Material strength per ISO 9626	Pass
Activated pressure leak	No leak when subjected to pumping pressures up to 20psi under normal delivery conditions and occluded fluid path conditions	Pass
Penetration force	Needle and catheter shall penetrate a 0.025 inch thick membrane with a speed of 50mm/min. and a force of less than 0.8N	Pass
Needle retention	No separation of the needle from the cap when subjected to a minimum force of 10N (ISO 10555- 1, Annex B)	Pass
Catheter retention	No separation of the catheter from the base when subjected to a minimum force of 3N (ISO 8536-8)	Pass
Bond strength of tubing/fittings	No separation of the tubing assembly when subjected to a static tensile force of 15N for 15 sec.	Pass
Bond strength of tape/base	No separation of the tape from the base when subjected to a minimum force of 18N	Pass
Engagement force tubing cap/base	The cap locks on the base with a force less than 13N	Pass

Disengagement force tubing cap/base	The force to remove the tubing cap from the base is more than 13N	Pass
Occlusion test	No occlusion of the device when tested with a water flow at a hydrostatic pressure of 0.1 bar	Pass
Tape adhesion	Removal of adhesive from a stainless steel plate with a 90 degree peel force of minimum 2.5N (0.56lbs)	Pass

The following biocompatibility tests were completed on the subject device in accordance to ISO 10993-1 2009 with acceptable results:

- Cytotoxicity ISO MEM Elution Assay
- Hemolysis ASTM Assay Extract Method
- Acute Systemic Injection
- Guinea Pig Maximization Sensitization
- Intracutaneous reactivity study
- Bacterial Endotoxin

The Subject infusion sets were tested, and met all meet all acceptance criteria, for all the requirements as provided above. Based on the results Ypsomed concluded that the device performance is acceptable for the product.

10. Clinical Data

Clinical Data per 807.92(b)(2) was not required to establish substantial equivalence for these devices.

11. Conclusion

Ypsomed AG concludes based on the information presented that the subject infusion sets are substantially equivalent to the predicate device legally marketed in the US.