July 12, 2018

Conod Medical Co., Limited
℅ Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
9TH floor, R&D Building, No. 26, Qinglan Street, Planyu Distict
Guangzhou, Guangdong 510006
China

Re: K181276
Trade/Device Name: CONOD Enteral Feeding Sets
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PIF, KNT
Dated: May 15, 2018
Received: May 17, 2018

Dear Mike Gu:

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 and Part 809); 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey W. Cooper -S
2018.07.12 11:40:34
-04'00'

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K181276

Device Name
CONOD Enteral Feeding Sets

Indications for Use *(Describe)*
CONOD Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a piercing spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.

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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CONOD K181276

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

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Date prepared	Jul 10, 2018

2. DEVICE

Device Name:	CONOD Enteral Feeding Sets
Common/Usual Name:	Enteral Feeding Sets
Classification Name:	Gastrointestinal tube and accessories
Regulation number	21 CFR 876.5980
Regulation Class:	II
Product Code:	PIF, KNT

3. PREDICATE DEVICE

K150286, Medline Enteral Feeding Sets
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The CONOD Enteral Feeding Sets have three models, CONOD safety spike plus pump set, CONOD gravity feeding set and CONOD feeding pump set. The CONOD Feeding Pump Set (1200ml) and gravity feeding set both have a structure of a 1200ml formula bag with 100ml graduations and a protective closure cap. The difference is the former is droved by pump and the latter is droved by gravity. CONOD Safety spike plus Pump Set features a piercing spike used to connect the set to a prefilled container of enteral feeding solution. It is a single-use, non-sterile device.

5. INDICATIONS FOR USE

CONOD Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a piercing spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 6.1 Comparison with Predicate Device

Specification	Predicate Device	Proposed Device	Discussion of Differences
Device name	Medline Enteral Feeding Sets	CONOD Enteral Feeding Sets	
K number	K150286	K181276	
Indications for Use	Medline Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets may include a bag to contain the feeding solution and/or spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.	CONOD Enteral Feeding Sets are intended to dispense liquid nutrition (feeding solutions) at a user controlled rate. These enteral feeding sets interface with a patient's feeding tube and may use gravity or an enteral feeding pump to dispense feeding solution. The enteral feeding sets include a bag to contain the feeding solution and/or a piercing spike to connect to a pre-filled container. The device is used for infants, children, adolescents and adults.	same
Product code	PIF, KNT	PIF, KNT	Same
Classification regulation	21 CFR 876.5980	21 CFR 876.5980	Same
Device configurations	- Medline Enteral Feeding Pump Bag Set (1000ml) - Medline Enteral Feeding Pump Spike Set - Medline Enteral Feeding Gravity Bag Set (1000ml)	- CONOD Feeding Pump Set (1200ml) - CONOD Safety spike plus Pump Set - CONOD Gravity Feeding Set (1200ml)	similar
Assemble parts	- Enteral feeding bag, tubing, drip chamber, piercing spike, roller clamp and Distal Tip ENFit connectors.	- Enteral feeding bag, tubing, drip chamber, piercing spike, roller clamp and Distal Tip ENFit connectors.	Same

Specification	Predicate Device	Proposed Device	Discussion of Differences
Design feature	Non DEHP material sets featuring ISO 80369-3:2016 connector	Non DEHP material sets featuring ISO 80369-3:2016 connector	same
Materials	Same with the predicate device		Same
Prescription use or not	Prescription use	Prescription use	Same
Disposable or not	Disposable for single use	Disposable for single use	Same
Intended use time	No longer than 24 hours	No longer than 24 hours	same
Sterile or not	Non-sterile	Non-sterile	Same
Shelf-life	5 years	5 years	same
Available tube lengths	Pump set: 60cm+157cm Spike set: 60cm+157cm Gravity set: 170cm	Pump set: 60cm+157cm Spike set: 60cm+157cm Gravity set: 170cm	same

CONOD Enteral Feeding Sets has the same intended use and design specifications with the predicate device. CONOD Enteral Feeding Sets is substantial equivalent with the predicate device.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the CONOD Enteral Feeding Sets was conducted in accordance with the International Standard ISO 10993-1:2009, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Skin Irritation

The CONOD Enteral Feeding Sets are considered to contact indirectly with the human body for a duration of less than 24 hours. Testing for cytotoxicity, sensitization and skin irritation complied with ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. Testing demonstrates that the materials are non-cytotoxic, non-sensitizing, and non-irritating.

Performance testing

Performance testing was conducted on the CONOD Enteral Feeding Sets according to EN 1615, ISO 80369-3, ISO 11737 and IEC 62366, the tests are as follows:

a) Fluid leakage test
b) Stress cracking test
c) Resistance to separation from axial load test
d) Resistance to separation from unscrewing test
e) Resistance to overriding test
f) Disconnection by unscrewing test
g) Tensile Properties
h) Liquid leakage test
i) Flow rate test
j) Bioburden test
k) Usability test

Animal Study

The subject of this premarket submission, CONOD Enteral Feeding Sets, did not require animal studies to support substantial equivalence.

Clinical Study

The subject of this premarket submission, CONOD Enteral Feeding Sets, did not require clinical studies to support substantial equivalence.

8. CONCLUSION

The differences between the CONOD Enteral Feeding Sets and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the CONOD Enteral Feeding Sets should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Conod Medical concludes that the CONOD Enteral Feeding Sets is as safe and as effective as the predicate device.