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

April 3, 2017

U&U Medical Technology Co., Ltd
Black Wang
GM
Dongzhou Village, Hengshanqiao
Changzhou, Jiangsu 213119
China

Re: K160855
Trade/Device Name: U&U ENFit Enteral Syringe
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tubes and Accessories
Regulatory Class: II
Product Code: PNR
Dated (Date on orig SE ltr): October 18, 2016
Received (Date on orig SE ltr): October 20, 2016

Dear Black Wang:

This letter corrects our substantially equivalent letter of November 22, 2016

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,

Benjamin R. Fisher -S

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)*
K160855

Device Name
U&U ENFit Enteral Syringe

Indications for Use *(Describe)*
The U&U ENFit Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

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.

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

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Section_005 510(K) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

**K160855**

Date Prepared: 11. 22 .2016

### 1. Submitter Name and Address:

**Owner** Name: U&U Medical Technology Co., Ltd
Address: Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
RM C1-D 6/F WING HING IND BLDG 14 HING YIP ST KWUN TONG KLN HONG KONG
Contactor Name: Xuebo Wang
TEL: +86-13564751751
E-mail: Blackwang@tkmedical.com

**US Agent**:
Name: CARELIFE (USA) INC.
Address: 1580 Boggs Rd, Suite 500/600 Duluth GA 30096
TEL: 404 6612228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

### 2. Submission Devices Information:

Trade/Proprietary Name: U&U ENFit Enteral Syringe
Common Name: Gastrointestinal tube and accessories
Classification name: ENFit Enteral Syringes With Enteral Specific Connectors
Class: 2.
Review Panel: Gastroenterology/Urology.
Product codes: PNR
Submission Type: 510(k)
Regulation Number: 21 CFR § 876.5980

### 3. Predicate Devices Information:

| | |
|---|---|
| Trade Name: | NeoConnect Oral/Enteral Syringes With ENFit Connector (12 ML To 100 ML) And NeoConnect Low Dose Tip Oral/Enteral Syringes With ENFit Connector (0.5 ML To 6mL) |
| 510(K) Number: | K161039 |
| Company: | NeoMed, Inc. |

### 4. Devices Description:

The U&U ENFit Enteral Syringes are standard piston style syringes consisting of a syringe barrel, syringe plunger, syringe gasket, and supplied with or without a syringe tip cap. They are provided in varying sizes ranging from 1 mL to 60 mL nominal capacity. The integral syringe tip is a female connector which is compatible only with enteral access devices having male connectors to form a dedicated system that prevents wrong-route administration of fluids. They possess translucent barrels to provide visualization of fluid contents and volume.

## 5. Intended Use:

The U&U ENFit Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups.

## 6. Technological Characteristics:

Through comparisons between the submitted devices with the predicate devices as follows tables.

**Comparison Table**

| Element of Comparison | Submission Device | Predicate Device K161039 |
|---|---|---|
| **Intended Use** | The U&U ENFit Enteral Syringe is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups. | The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body enterally. It is intended to be used in clinical or home care settings by users ranging from clinicians to laypersons (under the supervision of a clinician) in all age groups. |
| **Principle of Operation** | Normal | Normal |
| **Syringe Capacity** | 1cc/ml to 60cc/ml | 0.5cc/ml to 100cc/ml |
| **Nozzle Type** | ISO 80369-3 | ISO 80369-3 |
| **Lubricant for Barrel** | Silicone Oil | Silicone Oil |
| **Barrel Transparency** | Transparent and Clear | Transparent and Clear |
| **Gradations Legibility** | Legible | Legible |
| **Materials**<br>**Barrel**<br>**Plunger**<br>**Piston** | <br>PP<br>PP<br>Silicone or Rubber | <br>PP<br>PP<br>Silicone |
| **Performances** | Conforms to ISO7886 ISO80369-3 | Conforms to ISO7886 ISO80369-3 |
| **Biocompatibility** | Conforms to ISO10993 (Part 1: Evaluation and testing, Part 5: Tests for in vitro cytotoxicity, Part 7: Ethylene oxide sterilization residuals, Part 10: Tests for irritation anddelayed-type hypersensitivity, Part 11: Tests for systemic toxicity) | Conforms to ISO10993 |
| **Labeling** | Meet the requirements of 21 CFR Part 801 | Meet the requirements of 21 CFR Part 801 |

## 7. Non-Clinical Tests performed on the subject device.

The proposed devices were tested per the following standards, to evaluate its performance.

• ISO7886-1 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
• ISO 80369-3 Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications

The test items include following

- Physical Performance - Diameter
- Physical Performance - Maximum Dead Space
- Physical Performance - Freedom Liquid and air leakage past piston
- Physical Performance - Force required to Operate plunger
- Physical Performance - Tolerance on graduated capacity (Dose accuracy)
- Syringe Tip (ISO 80369-3 female connector)
  Fluid Leakage by pressure decay
  Fluid Leakage by falling drop positive pressure decay
  Stress Cracking
  Resistance to separation from axial load
  Resistance to separation from unscrewing
  Resistance to overriding
  Disconnection by unscrewing
  Low Dose Tip Misconnection Analysis Report
  Low Dose Dimension Analysis Report

Biocompatibility

Conforms to ISO10993
Part 1: Evaluation and testing,
Part 5: Tests for in vitro cytotoxicity,
Part 7: Ethylene oxide sterilization residuals,
Part 10: Tests for irritation and delayed- type hypersensitivity,
Part 11: Tests for systemic toxicity

## 8. Conclusion:

The materials, performance, and operational features of both the subject device and the predicate device are substantially equivalent.

END