February 22, 2018

U&U Medical Technology Co., Ltd
Xuebo Wang
Gm
Dongzhou Village
Hengshanqiao
Changzhou, 213119 CN

Re: K171823
Trade/Device Name: U&U Indicator Tape and Strip
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: December 26, 2017
Received: January 4, 2018

Dear Xuebo Wang:

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.

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.

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,

Michael J. Ryan -S

for 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)*
K171832

Device Name
U&U Indicator tape and strip

Indications for Use *(Describe)*
The U&U Sterilization indicator tapes and strips are designed to demonstrate that the unit or load has been exposed to a sterilization process and to distinguish between processed and unprocessed units or loads. After steam sterilization, the chemical indicator lines will show a visual color change from off yellow to Dark brown/Black.

Use the U&U Sterilization indicator tapes and strips in steam sterilization processes described below.

1. 121°C, 30 minutes; Gravity Steam
2. 132°C, 4 minutes; Dynamic Air Removal Steam
3. 135°C, 3 minutes; Dynamic Air Removal Steam

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K171823 510(K) Summary

This 510(k) summary is being submitted in accordance with 21 CFR §807.92

Date Prepared: **2017-12-12**
Submission Numbers for 510(k) Submission: K171823

1. Submitter Name and Address:

Name: U&U Medical Technology Co., Ltd
Address: Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
RM EE1092 1/F Building 1, No 1755, HONGMEI Road, Shanghai, China
Contactor Name: Xuebo Wang
TEL: +86-13564751751
E-mail: wangxuebo_11@hotmail.com

US Agent:
Name: U&U Medical Inc..
Address: 1580 Boggs Rd, Suite 500, Duluth, GA 30096
TEL: 404 426 1248
Contact person : Ms. LI QIAN li@UU-Medicalus.com

2. Submission Devices Information:

Trade/Proprietary Name: U&U Indicator Tape and Strip
Common Name: Process Indicator Tape, Process indicator Strip
Classification name: indicator, physical/chemical sterilization process
Class: II, 21CFR 880.2800(b)
FDA review panel code: General Hospital
Product code: JOJ

3. Predicate Devices Information:

Trade Name: 3m Autoclave Tapes
510(K) Number: K932129
Manufacturer: 3M Health Care

Trade Name: 3m Steam Sterilization Indicator
510(K) Number: K801057
Manufacturer: 3M Health Care

4. Device Description:

The U&U Sterilization Indicator Tape is designed for use with steam sterilization as a method of securing packs and identifying processed from unprocessed items.

The U&U Sterilization Indicator Strip is a paper strip printed with a chemical indicator ink that turns from yellow to dark brown/black when exposed to the steam sterilization process. It is designed to indicate whether steam has penetrated to the point of placement of the strip, An internal chemical indicator should be used inside each pack to be sterilized.

Model Number：

Ref Number	Model Number	Description	Size
UUST0001	UUST	U&U Sterilization Indicator Tape	12mm X 55m
UUST0002	UUST	U&U Sterilization Indicator Tape	18mm X 55m
UUST0003	UUST	U&U Sterilization Indicator Tape	24mm X 55m
UUST0004	UUST	U&U Sterilization Indicator Tape	48mm X 55m
UUSS0001	UUSS	U&U Sterilization Indicator Strip	15mm X 200mm

5. Intended Use:

The U&U Sterilization indicator tapes and strips are designed to demonstrate that the unit or load has been exposed to a sterilization process and to distinguish between processed and unprocessed units or loads. After steam sterilization, the chemical indicator lines will show a visual color change from off yellow to Dark brown/Black.

Use the U&U Sterilization Indicator tapes and strips in steam sterilization processes described below.

1. 121℃, 30 minutes; Gravity Steam
2. 132℃, 4 minutes; Dynamic Air Removal Steam
3. 135℃, 3 minutes; Dynamic Air Removal Steam

6. TECHNOLOGICAL CHARACTERISTICS COMPARISON:

.
the U&U Sterilization Indicator Tape and Strip Comparison table:

Element of Comparison	Submission Device	Predicate Device K932129	Predicate Device K801057
Intended Use	U&U Sterilization indicator tapes are designed to demonstrate that the unit or load has been exposed to a sterilization process and to distinguish between processed and unprocessed units or loads..	3m Autoclave Tapes is a single use device intended to be used to exposed to the sterilization process and to distinguish between processed and unprocessed packs..	3m Steam Sterilization Indicator is a single use device intended to be used to exposed to the sterilization process and to distinguish between processed and unprocessed packs..
Class	Class 1	Class 1	Class 1
Device Design	Crepe paper printed with indicator lines. Provided in beige colored	Crepe paper printed with indicator lines. Provided in beige colored	paper printed with indicator lines. Provided in beige colored
Size	Tape: (12mm, 18mm ,24mm and 48mm) X 55m Strip: 15mm X 200mm	(12mm, 18mm ,24mm and 48mm) X 55m	15mm X 200mm
Indicator Agent	Indicator Ink	Indicator Ink	Indicator Ink
Endpoint Color	Dark brown/Black	Dark brown/Black	Dark brown/Black
Sterilization Method	Steam	Steam	Steam
Endpoint	121℃, 10 minutes; 132℃, 2 minutes; 135℃, 2 minutes;	121℃, 10 minutes; 134℃, 2 minutes;	121℃, 10 minutes; 134℃, 2 minutes;

Indictor Color Change Performance	Shall show a visible color change when exposure to endpoint parameters.	Shall show a visible color change when exposure to endpoint parameters.	Shall show a visible color change when exposure to endpoint parameters.
Recommended Storage Conditions:	Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents.	Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents.	Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents.
Shelf Life	After use the indicator will not change visually within 6 months within Recommended Storage Conditions.	After use the indicator will not change visually within 6 months within Recommended Storage Conditions.	After use the indicator will not change visually within 6 months within Recommended Storage Conditions.
Performance Standards	AAMI 11140-1	AAMI 11140-1	AAMI 11140-1

7. Non-Clinical Testing:

Validation of the U&U Sterilization Indicator Tape and Strip included performance testing in steam sterilizer, biocompatibility, storage condition, shelf life. All results, from testing meet the predetermined acceptance criteria.
All testing followed the FDA Guidance document for Industry and FDA Staff entitled, "Premarket Notification [5 10(k)] Submissions for Chemical Indicators,". And AAMI.ISO 11140-1: Sterilization of health care products — Chemical indicators Part 1: General requirements

8. Conclusion:

Based on the nonclinical tests performed the subject device is as safe, as effective and performs at least as well as the legally marketed predicate device, K932129 3m Autoclave Tapes and K801057 3m Steam Sterilization Indicator (21 CFR 880.2800 (b), Product code JOJ)