DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

Ecolab, Incorporated
Jennifer Willner
Director, Regulatory Affairs - Healthcare
370 Wabasha Street North
St. Paul, Minnesota 55102

Re: K142080
Trade/Device Name: Non-Sterile ORS Warming and Slush Drapes
Regulatory Class: Unclassified
Product Code: LHC
Dated: July 30, 2014
Received: July 31, 2014

Dear Ms. Willner:

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,

Erin I. Keith -S

Erin Keith, M.S.
Division 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)*
K142080

Device Name
Non-Sterile ORS Warming and Slush Drapes.

Indications for Use *(Describe)*
The ORS drape is a single-use equipment cover intended for use during various surgeries where warm irrigation, slush and/or cold solution is required.

The following models are included: ORS-100N, ORS-300N, ORS-301N, ORS-320N, ORS-321N, ORS-330N and ORS-188231N.

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)*

Sajjad H. Syed -S

Digitally signed by Sajjad H. Syed -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed -S, 0.9.2342.19200300.100.1.1=2000601742
Date: 2014.08.26 17:00:38 -04'00'

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K140280 – 510(K) SUMMARY

Section 5: 510(k) Summary

Non-Sterile ORS Warming and Slush Drapes

As required by 21 CFR 807.92.

Date: July 30, 2014

Administrative Information

Submitter: Ecolab, Inc.

Establishment Registration Number: 1043582

Contact Person: Jennifer Willner, RAC
370 Wabasha Street North
St. Paul, MN 55102-1390
Director, Regulatory Affairs - Healthcare
651.250.4348

Device Identification

Device Name:	Non-Sterile ORS Warming and Slush Drapes
Common Name:	Equipment Cover
Device Classification Name:	Warmer, Irrigation Solution
Device Classification:	Unclassified
Classification Product Code:	LHC
Panel:	General and Plastic Surgery
Classification Regulation:	Pre-amendment
Performance Standards:	No Recognized Consensus Standards
Predicate Device:	ORS-1000LD [covers ORS-100, ORS-300, ORS-301, ORS-188231] cleared on 06/27/2002 via K021288 and ORS-3000LD [covers ORS-320, ORS-321, ORS-330] cleared 11/13/2002 via K023282

Device Description

The Non-Sterile ORS Warming and Slush Drapes are single-use equipment covers intended for use during various surgeries where warm irrigation, slush and/or cold solution is required. These equipment drapes consist of a polyurethane film base material manufactured to protect ORS surgical fluid warmers and slush machines from contamination during various procedures throughout the clinical setting.

These equipment drapes come in a variety of sizes and shapes to allow the device to properly fit ORS surgical fluid warmers and slush machines.

Special 510(k) Discussion

This Special 510(k) submission requests clearance for the manufacture and distribution of non-sterile ORS drapes from an identical subset of cleared sterile ORS devices. The non-sterile drapes will be sold in bulk packaging to other secondary processors, including kit packers, who will then package, label and sterilize the drapes prior to distribution to end users. The fundamental scientific technology of these equipment drapes remains unchanged. The Substantial Equivalence Table (Table 5-1) is provided below.

Table 5-1: Substantial Equivalence

Property or Characteristic	**Proposed Device**	**Predicate Device (Warming Drapes)**	**Predicate Device (Slush Drapes)**
510(k) No.	**This 510(k) Submission**	**K021288**	**K023282**
Device Name	**Non-Sterile ORS Warming and Slush Drapes** (includes: ORS-100N, ORS-300N, ORS-301N, ORS-320N, ORS-321N, ORS-330N and ORS-188231N)	ORS-1000LD (includes: ORS-100, ORS-300, ORS-301, and ORS-188231)	ORS-3000LD (includes: ORS-320, ORS-321, and ORS-330)
Indications for Use	The ORS drape is a single-use equipment cover intended for use during various surgeries where	The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer.	The ORS-3000LD is an equipment cover for the ORS-1075LD Hush-Slush® machine. This is a single use

Property or Characteristic	Proposed Device	Predicate Device (Warming Drapes)	Predicate Device (Slush Drapes)
	warm irrigation, slush and/or cold solution is required.	This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.	product supplied sterile. This device is intended for use during various surgeries where slush and/or cold solution is required.
Conditions of Use	Rx Only, Single Use, Disposable	Identical	Identical
Materials	Polyurethane Film Polypropylene skirt for ORS-188231N only	Identical	Identical
Principle of Operation	Covers surgical solution warmers and/or slush machines	Covers surgical solution warmers	Covers surgical solution warmers and/or slush machines
Packaging	Bulk packaged in poly bag in quantities up to 24	Individually packaged in poly/Tyvek peel pouches	Individually packaged in poly/Tyvek peel pouches
Sterilized	No; intended to be sterilized before distribution to end user	Yes; provided in sterile condition via EO at SAL 10^{-6}	Yes; provided in sterile condition via EO at SAL 10^{-6}

Statement of Equivalence

The Non-Sterile ORS Warming and Slush Drapes perform as intended using the identical principles of operation as the predicate device(s). Differences between the Non-Sterile ORS Warming and Slush Drapes and the sterile versions do not raise any new questions of safety or efficacy when secondary processors finish the product as instructed. Based on the risk analysis, review of the product labeling, and successful performance and safety testing, the Non-Sterile ORS Warming and Slush Drapes are substantially equivalent to the legally marketed Sterile ORS Warming and Slush Drapes (K021288 and K023282). The fundamental scientific technology of the device remains unchanged.

Performance Data Summary

Table 5-2: Performance Data Summary of the Non-Sterile ORS Warming and Slush Drapes

Requirement	Specification	Method	Result
Functional Performance Requirements (of selected drape types)	Dimensional Requirements: ORS-301N (66 in. x 52 in.) ORS-321N (66 in. x 52 in.) ORS-330N (66 in. x 44 in.) ORS-188231N, Skirted (44 in. x 44 in. x 36 in.)	Representative drapes were chosen to cover all drape types. Drapes selected: ORS-301N (largest size), ORS-188231N (only skirted drape), ORS-321N (largest size Disc drape), ORS-330N (largest Plate drape) Acceptable results following visual inspection during V&V testing; VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
	Drape remains intact (free from holes or other defects that would compromise the sterile barrier)	Acceptable results following visual inspection during V&V testing; VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
	Disc/Plate must stay attached to drape during use	Acceptable results following V&V testing (based on sterile product testing); VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
	Drape/Device must attach to Slush Machine	Acceptable results following V&V testing (based on sterile product testing); VVR-14-0002 V&V Summary Report, Project 8 Track	Pass
Packaging	Packaging Configuration: 24 per case, double poly bagged	Packaging Configuration per: ORS-301N_DWG ORS-321N_DWG ORS-330N_DWG ORS-188231N_DWG; acceptable results following visual inspection during V&V testing; documented in V&V Summary Report VVR-14-0002	Pass
	Product must be received by customer with folds intact	Acceptable results following visual inspection during V&V testing; documented in V&V Summary Report VVR-14-0002	Pass
	Simulated Distribution Test	ASTM D4169-09 (Distribution Cycle 2, Assurance Level 1) Simulated Distribution Test (PKG 001F)	Pass

Requirement	Specification	Method	Result
		documented in Packaging Engineering Report # REPT-18430	
	Inspection for Drape Damage	Acceptable results following visual inspection during V&V testing; documented in V&V summary report VVR-14-0002	Pass
Labeling	Master carton label is present and per specification	Master label specifications: ORS-301NMASTER ORS-321NMASTER ORS-330NMASTER ORS-188231NMASTER Acceptable results following visual inspection during V&V testing; documented in V&V summary report VVR-14-0002	Pass
	Ink (non-smudge/smear)	Acceptable results following visual inspection during V&V testing; documented in V&V summary report VVR-14-0002	Pass
	Insert Sheet/IFU is present and per specification	Insert Sheet/IFU specifications: 1) ORS-WARMER DRAPE_2014-5/NEW INSERT SHEET (ORS-100N, ORS-300N, ORS-301N, ORS-188231N) 2) ORS-320N/ORS-321N_2014-5/NEW SLUSH/WARMER DISC-DRAPE INSERT SHEET 3) ORS-330N_2014-5/NEW SLUSH/WARMER PLATE DRAPE INSERT SHEET	Pass
	Product Identification label includes product code and Ecolab Logo	Product Identification label specification: ORS-301NMISC ORS-188231NMISC ORS-321NMISC ORS-330NMISC	Pass