



Food and Drug Administration
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January 15, 2016

Ecolab, Inc.
Ms. Jennifer Willner
Sr. Director Regulatory Affairs
370 Wabasha Street North
Saint Paul, Minnesota 55102

Re: K152522

Trade/Device Name: ORS-3000LD Slush Drapes, ORS-1000LD Fluid Warming Drapes
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LHC
Dated: December 7, 2015
Received: December 8, 2015

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" (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,

 Tina Kiang -
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for 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

Enclosure

Indications for Use

510(k) Number (if known)
K152522

Device Name
ORS-3000LD Slush Drapes
ORS-1000LD Fluid Warming Drapes

Indications for Use (Describe)

The ORS-3000LD is an equipment cover for the ORS-1075LD Hush-Slush® machine. This is a single use product supplied sterile. This device is intended to be used during various surgeries where slush and/or cold solution is required.

Models: ORS-130/ORS-130-16, ORS-320/ORS-320-16, ORS-321/ORS-321-16, ORS-325/ORS-325-16,
330/ORS-330-16, ORS-331/ORS-331-16

The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.

Models: ORS-100, ORS-110, ORS-300, ORS-301

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.

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Section 5: 510(k) Summary K152522

ORS Fluid Warming and Slush Drapes

As required by 21 CFR 807.92.

Date: December 7, 2015

Administrative Information

Submitter: Ecolab, Inc.

**Establishment
Registration Number:** 1043582

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

Device Identification

Device Name: ORS-3000LD Slush Drapes
ORS-1000LD Warming Drapes

Common Name: Equipment Cover

Device Classification Name: Warmer, Irrigation Solution

Device Classification: Unclassified

Classification Product Code: LHC

Panel: General Hospital

Classification Regulation: Pre-amendment

Performance Standards: No Recognized Consensus Standards

Predicate Device: K021288: ORS-1000LD
Covers ORS-100, ORS-110, ORS-300, and ORS-301

K023282: ORS-3000LD

Covers ORS-130, ORS-320, ORS-321, ORS-325, ORS-330, and ORS-331

Intended Use

The ORS-3000LD is an equipment cover for the ORS-1075LD Hush-Slush® machine. This is a single use product supplied sterile. This device is intended to be used during various surgeries where slush and/or cold solution is required.

Models: ORS-130/ORS-130-16, ORS-320/ORS-320-16, ORS-321/ORS-321-16, ORS-325/ORS-325-16, 330/ORS-330-16, ORS-331/ORS-331-16

The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.

Models: ORS-100, ORS-110, ORS-300, ORS-301

Device Description

The ORS Fluid Warming and Slush Drapes are sterile, single-use equipment covers intended for use during various surgeries where warm irrigation, slush and/or cold solution is required. The ORS Fluid Warming drapes consist of a polyurethane film base material manufactured to protect ORS surgical fluid warming consoles. The ORS Surgical Slush drapes consist of a polyurethane film base secured to a polycarbonate disc or plate manufactured to protect ORS surgical slush machines from contamination during various procedures throughout the clinical setting.

The ORS Fluid Warming and Slush Drapes come in a variety of sizes and shapes specifically designed for safe use and proper fit on ORS Fluid Warming Consoles and Slush Machines.

Special 510(k) Discussion

This Special 510(k) submission requests FDA clearance for the manufacture and distribution of ORS Fluid Warming and Slush Drapes in an alternative packaging configuration. Specifically, Ecolab has identified an improvement opportunity in changing from the current poly-Tyvek pouch to a header bag as the primary sterile barrier package for the ORS Fluid Warming and Slush Drapes. The fundamental scientific technology of the drapes remains unchanged.

The Substantial Equivalence Table 5-1 is provided below.

Table 5-1: Substantial Equivalence Summary

Property or Characteristic	Proposed Device	Predicate Device (Warming Drapes)	Predicate Device (Slush Drapes)
510(k) No.	This 510(k) Submission	K021288	K023282
Device Name	ORS-1000LD Fluid Warming Drapes and ORS-3000LD Slush Drapes (includes: ORS-100, ORS-110, ORS-130/ORS-130-16, ORS-300, ORS-301, ORS-320/ ORS-320-16, ORS-321/ORS-321-16, ORS-325/ ORS-325-16, ORS-330/ORS-330-16, and ORS-331/ORS-331-16)	ORS-1000LD (includes: ORS-100, ORS-110, ORS-300, and ORS-301)	ORS-3000LD (includes: ORS-130, ORS-320, ORS-321, ORS-325, ORS-330, and ORS-331)
Indications for Use	<p>The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.</p> <p>The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution</p>	<p>The ORS-1000LD Leak Detection Drape is an equipment cover for the ORS-2000LD Solution Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required.</p>	<p>The ORS-3000LD is an equipment cover for the ORS-1075LD Hush-Slush[®] machine. This is a single use product supplied sterile. This device is intended for use during various surgeries where slush and/or cold solution is required.</p>

Property or Characteristic	Proposed Device	Predicate Device (Warming Drapes)	Predicate Device (Slush Drapes)
	Warmer. This is a single use product supplied sterile. This device is intended for use during various surgeries where warm irrigation solution is required		
Conditions of Use	Rx Only, Sterile, Single Use, Disposable	Identical	Identical
Materials	Polyurethane Film and Polycarbonate disc/plate for Slush drapes only	Polyurethane Film	Polyurethane Film and Polycarbonate disc/plate
Principle of Operation	Covers surgical solution warmers and/or slush machines	Covers surgical solution warmers	Covers surgical solution warmers and/or slush machines
Packaging	Individually packaged in poly header bags	Individually packaged in poly/Tyvek peel pouches	Individually packaged in poly/Tyvek peel pouches
Sterilized	Yes; provided in sterile condition via EO at SAL 10^{-6}	Yes; provided in sterile condition via EO at SAL 10^{-6}	Yes; provided in sterile condition via EO at SAL 10^{-6}

Performance Data Summary

A risk assessment was performed per ISO 14971 and the following tests were determined to be needed to verify and validate the changes made to the packaging.

Table 5-2: Summary of Design Verification Testing and Other Supporting Evidence

Test	Rep. Part(s)	Requirement	Results	Pass (Y/N)
EO Residuals	ORS-321	EO shall not exceed 4 mg	2.9 mg	Yes

Test	Rep. Part(s)	Requirement	Results	Pass (Y/N)
(ISO 10993-7)	(flat pack; 24/case)	ECH shall not exceed 9 mg	None recovered	Yes
		Cycle 48 Processing Group	24 hours aeration	Yes
Sterilization Cycle Temp/RH comparison to current pouch	ORS-321 (file pack; 24/case)	Seal strength must meet a minimum load of 4.4 N (1 lbf) for a 1" wide sample (LAB-ALPH-025)	Pre Seal Current (0800700094) =15 of 15 pass	Yes
			Post Seal Current (0800700094) = 15 of 15 pass	Yes
			Pre Seal New (POU708)= 15 of 15 pass	Yes
			Post Seal New (POU708)= 15 of 15 pass	Yes
		Current Pouch (080700900094) and POU708 header bag meet 100-125°F (37.8-51.6°C) and 45-80% RH by the end of preconditioning	Temp = 94-7- 110.2 °F	No*
			RH= 46.8- 54.0%	Yes
		Current Pouch (080700900094) and POU708 header bag meet 120-140°F (48.9-60°C) during EO gas dwell within ± 2 minutes of each other.	Temp =96.4- 110.1°F	No*
			RH =47.2 - 47.5%	Yes
Sterilization Adoption	ORS-301 (flat pack; 24/case)	Approved FORM 0424 /JX-092	Approved FORM 0424/JX-092 and supporting documents attached to the report	Yes
	ORS-321 (flat pack; 24/case)			Yes
ISO 11607-1 transport challenge package integrity testing	ORS-301 (flat pack; 24/case)	All samples must complete the entire distribution sample w/ no damage or degradation to the product that impacts product functionality or compromises sterility. Labels must be attached and legible. ASTM D4169-14	3 of 3 Pass	Yes
		There shall be no evidence of dye completely penetrating through a seal creating an open path through the entire seal width via a channel of dye. ASTM F3039-13	22 of 22 Pass	Yes
		There shall be no evidence of dye completely penetrating through a seal creating an open path through the entire seal width via a channel of dye ASTM F1929 – 12	22 of 22 Pass	Yes
		There shall be no evidence of a constant stream of bubbles penetrating through the seal or material creating a path through package seal or material ASTM F2096-11	22 of 22 Pass	Yes
		Mean peak load equal to or greater than 1.0 lbf. ASTM F88-09	Seal A = 22 of 22 Pass	Yes
			Seal B= 22 of 22 Pass	Yes
Seal C= 22 of 22 Pass	Yes			

Test	Rep. Part(s)	Requirement	Results	Pass (Y/N)
			Seal D= 22 of 22 Pass	Yes
	ORS-321 (flat pack; 16/case)	All samples must complete the entire distribution sample w/ no damage or degradation to the product that impacts product functionality or compromises sterility. Labels must be attached and legible. ASTM D4169-14	3 of 3 Pass	Yes
		There shall be no evidence of dye completely penetrating through a seal creating an open path through the entire seal width via a channel of dye. ASTM F3039-13	22 of 22 Pass	Yes
		There shall be no evidence of dye completely penetrating through a seal creating an open path through the entire seal width via a channel of dye ASTM F1929 – 12	22 of 22 Pass	Yes
		There shall be no evidence of a constant stream of bubbles penetrating through the seal or material creating a path through package seal or material ASTM F2096-11	22 of 22 Pass	Yes
		Mean peak load equal to or greater than 1.0 lbf. ASTM F88-09	Seal A = 22 of 22 Pass	Yes
			Seal B= 22 of 22 Pass	
	Seal C= 22 of 22 Pass			
	Seal D= 22 of 22 Pass			
Packaging Shelf Life Assessment	POU708 & POU709 Header Bags	Assessment of new packaging materials (POU708 & POU709) against ISO 11607-1 guidelines	Equivalent to RBA229 KYPHOPLASTY/VERTERBOPLASY DRAPE WITH RADIATION SHIELD as a representative product packaging. 4 years accelerated.	Assessment allows for 4 years accelerated. No additional testing required
Biocompatibility Assessment, ISO-11607-1	POU708 Header Bag	Assessment of Biocompatibility of ORS-321 Header Bag POU708	POU708 will not adversely impact the biocompatibility of the drape (Ref ORS-400 Testing)	N/A however assessment assures biocompatibility

*The temperature results, pre-conditioning, for both current pouch and the POU708, did not meet the acceptance criteria of the protocol. However, it was determined that the pre-conditioning temperature acceptance criteria were inappropriate for this assessment. The temperature penetration into the POU708 met or exceeded the temperature penetration into the incumbent 080700094 pouch. The performance of the POU708 during gas dwell met the acceptance criteria indicating that the steam penetrated the candidate header bag comparable to the incumbent 080700094, thus not having an adverse impact on sterility assurance

Conclusion

The ORS Fluid Warming and Slush Drapes perform as intended using the identical principles of operation as the predicate device(s). Differences between the packaging configurations do not raise different questions of safety and effectiveness. Based on the risk analysis and successful packaging performance testing, the ORS Fluid Warming and Slush Drapes are substantially equivalent to the legally marketed ORS Fluid Warming and Slush Drapes (K021288 and K023282). The fundamental scientific technology of the devices remain unchanged.