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

Quotient Medical
% Ms. Marilyn Lockhart
President
Lockhart Regulatory Services, Inc.
1860 Appleby Line, Suite 348
Burlington, Ontario L7L 7H7
CANADA

January 13, 2016

Re: K151070
Trade/Device Name: Sonishield™ 100 Antimicrobial Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: January 4, 2016
Received: January 11, 2016

Dear Ms. Lockhart:

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K151070

Device Name
Sonishield™ 100 Antimicrobial Ultrasound Gel

Indications for Use *(Describe)*
Sonishield™ 100 Antimicrobial Ultrasound Gel is intended for general use as a non-sterile transmission media for acoustically coupling a transducer to a human body surface during external and therapeutic diagnostic ultrasound imaging procedures. It is placed on the patient's skin prior to initiating an ultrasound examination. It is indicated for prescription use only.

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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510(k) Summary

Sonishield 100 Antimicrobial Ultrasound Gel

Common name: Ultrasound gel

MUI Product code

Class II device,

21 CFR 892.1570

Traditional 510(k) Submission

April 15, 2015

General Information

-510(k) owner's name:

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Burlington, Ontario, Canada L7N 3N2
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-Contact person:

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Burlington, Ontario L7L 7H7
Canada.
Telephone: 905-635-2855

-Prepared on March 20, 2015.

Device name

-Trade name

Sonishield™ 100 Antimicrobial Ultrasound Gel

-Common name

Ultrasound gel

-Classified name

Diagnostic ultrasonic transducer/acoustic gel
(21 CFR § 892.1570, Product code MUI)

Predicate devices

-Ecogel 100 Ultrasound Gel (K961757)
-Konix® Ultrasound Gel (K101952)

Device Description

Sonishield™ 100 Antimicrobial Ultrasound Gel consists of deionized water, hydroxyethylcellulose, propanediol and benzalkonium chloride. It is a type of conductive medium (i.e.) scanning gel used in ultrasound therapeutic and diagnostic imaging techniques. A scanning gel acts as a couplant that provides an acoustic pathway between the transducer and the skin. In addition, the gel eliminates air (a disruptive influence) from the interface and adapts the contours of the probe to the skin.

The major characteristics of Sonishield™ 100 Antimicrobial Ultrasound Gel include:

- Hypoallergenic, non-irritating
- Water soluble, non-staining and easily cleanable
- Does not contain oil or fatty matter
- Free from formaldehyde and salt
- No toxic effects
- Produced as a completely harmless material
- Has no odor
- Vacuum treated production
- Does not damage the probe
- Does not contain air bubbles
- pH level ranges from 4.5 to 6.5 at 25^0C

Intended use

Sonishield™ 100 Antimicrobial Ultrasound Gel is intended for general use as a non-sterile transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin prior to initiating an ultrasound examination. It is indicated for prescription use only.

Technological characteristics

Sonishield™ 100 Antimicrobial Ultrasound Gel has substantially the same technological characteristics as the predicate devices. The three products are compared in the table below:

Substantial Equivalence Discussion

Subject	Sonishield™ 100 Antimicrobial Ultrasound Gel	Ecogel 100 Ultrasound Gel	Konix® Ultrasound Gel
Intended Use	External	External	External
Ingredients	Salt free	Salt free	Salt free
	Dye free	Dye free	Dye free
	Alcohol free	Alcohol free	Alcohol free
	Formaldehyde free	Formaldehyde free	Formaldehyde free
	Perfume free	Perfume free	Perfume free
Physical Properties	Twist cap for accurate dispensing	Twist cap for accurate dispensing	Twist cap for accurate dispensing
	Flip-top can for quick refilling	Flip-top can for quick refilling	Flip-top can for quick refilling
Chemical Properties	Very high clarity	Good clarity	
	Hypoallergenic, bacteriostatic, non-sensitizing	Hypoallergenic, bacteriostatic, non-sensitizing	Hypoallergenic, non-irritating
	pH 4.5 – 6.5	pH 6.5 ± 0.75	pH 6.5 ± 0.75
	Density (g/mL) = 1.009	Density (g/mL) = 0.99	Density (g/mL) = 0.983
	Very clear screen image with high viscosity and vacuum process. No rapid melting from high-viscosity gel.	It has low viscosity. It melts immediately from low viscosity	Very clear screen image with high viscosity and vacuum process. No rapid melting from high-viscosity gel.
	Viscosity 80,000 – 120,000 CPS	Viscosity 35,000 – 40,000 CPS	Viscosity 100,000 – 120,000 CPS
	Boiling point >200^{0}C	Boiling point 100^{0}C	Boiling point >200^{0}C
	Water soluble high MW polymer	Water soluble high MW polymer	Water soluble high MW polymer
	No irritation	No irritation	No irritation
Process	It has a rapid manufacturing process	Normal process	a rapid manufacturing process
	Sonishield™ employs a soft bottle for ease of use.	Standard bottle	employs a soft bottle for ease of use
	Sonishield™ production employs a closed-loop system so there is no pollution transmission. Product is manufactured very cleanly.	Normal process	production employs a closed-loop system so there is no pollution transmission. Product is manufactured very cleanly.
	Standard production area	Standard production area	Standard production area

Subject	Sonishield™ 100 Antimicrobial Ultrasound Gel	Ecogel 100 Ultrasound Gel	Konix® Ultrasound Gel
	Standard process manufactured to release specifications.	Standard process	Manufactured in a clean room (1/100000 class)
Label	Standard information on polyethylene label to prevent loss of lettering	Standard information	Standard information on polyethylene label to prevent loss of lettering
Design	Bottle diameter designed to be compatible with ultrasound device. Bottle cap is designed for ease of opening and closing with one hand.	Conical cap	Bottle diameter designed to be compatible with ultrasound device. Bottle cap is designed for ease of opening and closing with one hand.
Safety	Sonishield™ label contains appropriate warnings and characteristics (Latex-free, PVC-free)	Standard information	label contains appropriate warnings and characteristics (Latex-free, PVC-free)
Environment of use	Hospital	Hospital	Hospital
Target population	Pediatric and adult	Pediatric and adult	Pediatric and adult
Anatomical site	Body (abdomen)	Body (abdomen)	Body (abdomen)
Use	Multiple uses	Multiple uses	Multiple uses
Material (package)	Polyethylene	Polyethylene	Polyethylene
Patient contact materials	Probe	Probe	Probe
Energy type	Electricity only for the ultrasound device	Electricity only for the ultrasound device	Electricity only for the ultrasound device

Non-clinical performance

Acoustic:

Sonishield™ 100 Antimicrobial Ultrasound Gel was evaluated for its acoustic performance. Results indicate that the acoustic properties of the gel are:

1. Virtually identical to that of human skin.
2. Similar to other coupling gels commonly used in the United States.

The acoustic properties of Sonishield™ 100 Antimicrobial Ultrasound Gel are as follows:

- Sound velocity (m/sec) at 30^0C — 1497
- Density (kg/m^3) at 30^0C — 1.023 X 10^{-3}
- Acoustic impedance (kg/m^2 sec) at 30^0C — 1.53
- Attenuation coefficient as a function of frequency, a/f (dB/cm-MHz) — 0.04 ± 0.0042 f

The acoustic properties of the predicate gels are virtually identical. Those properties for the Konix® Ultrasound Gel are provided below:

- Sound velocity (m/sec) at 30^0C — 1516
- Density (kg/m^3) at 30^0C — 0.98X 10^{-3}
- Acoustic impedance (kg/m^2 sec) at 30^0C — 1.49
- Attenuation coefficient as a function of frequency, a/f (dB/cm-MHz) — <0.05 f

Antimicrobial Effectiveness Testing:

Using USP <51> Category 2 as a guide, antimicrobial effectiveness testing performed on Sonishield™ 100 Antimicrobial Ultrasound Gel demonstrated the bacteria (S. Aureus, Pseudomonas aeruginosa, E.coli, S.Aureus (MRSA) and K. pneumoniae) showed a log reduction greater than 4 from the initial count at 14 days and at 28 days.

Animal tests:

Biocompatibility (ISO 10993-10) testing was conducted for Skin Irritation and Skin Sensitization. Conclusions from these studies: Sonishield™ 100 Antibacterial Ultrasound Gel was found to be non-sensitizing and non-irritating.

Clinical tests:

In clinical studies using Sonishield™ 100 Antimicrobial Ultrasound Gel, the following were concluded:

-In a two part study of the Tolerance of Sonishield™ 100 Antimicrobial Ultrasound Gel, the product produced no signs of cutaneous irritation.

-In another study, (HRIPT with 55 volunteers), no pertinent reaction to the test product was observed during the challenge phase of the study and the product can be considered as hypo-allergenic. In the induction phase of the study, 9 of 55 volunteers showed “barely noticeable” reactions, 1 of 55 volunteers showed Grade 1 and 2 volunteers showed Grade 2 erythema, while all other volunteers had no reaction to the gel during the induction phase of the study.

CONCLUSIONS

The above-referenced comparisons of the technological and non-clinical performance characteristics indicate that the Sonishield™ Antimicrobial 100 Ultrasound Gel is nearly identical to the predicate gels and certainly substantially equivalent to both and other coupling gels commonly used in the United States.