K101952

510(k) Summary

MAY 27 2011

General information

- **510(k) owner's name, etc.**

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- **Contact person**

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- **Prepared on** May 25, 2011

Device names

Trade name

Konix® Ultrasound Gel

Common name

Acoustic gel

Classified name

Diagnostic ultrasonic transducer/acoustic gel

(21 CFR § 892.1570, Product code ITX)

Predicate device

Eco-Med Pharmaceuticals' Ecogel 100 Ultrasound Gel (K961757)

Device description

Konix® Ultrasound Gel consists of deionized water, carbomer, triethanolamine, monopropylene glycol, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3 one and is a type of conductive medium, i.e., scanning gel, used in ultrasound diagnostic 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 Konix® Ultrasound Gel include:

- Hypoallergenic, non-irritating
- Water soluble, non-staining and easily cleanable
- Does not contain oil and fatty matter
- Free from formaldehyde and salt
- No toxic effects
- Produced as a completely harmless material
- No smell
- Vacuum treated production
- Not-damageable to the probe
- Does not contain air bubbles
- pH level is 7

Intended use

Konix® Ultrasound Gel is intended for general use as a nonsterile transmission media for acoustically coupling a transducer to a human body surface during external, 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

Konix® Ultrasound Gel has substantially the same technological characteristics as the predicate device. The two are compared below.

Substantial Equivalence Discussion

	KONIX® ULTRASOUND GEL	ECOGEL 100 ULTRASOUND GEL (K961757)
Intended Use	**External**	**External**
INGREDIENTS	Salt free	Salt free
	Dye free	Green color
	Alcohol free	Alcohol free
	Formaldehyde free	Formaldehyde free
	Perfume free or not free (with IFRA certificate)	Perfume free
PHYSICAL PROPERTIES	Twist cap for accurate dispensing	Twist cap for accurate dispensing
	Flip-top can for quick refilling	Flip-top cap for quick refilling
CHEMICAL PROPERTIES	Very high clarity	Good clarity
	Hypoallergenic, bacteriostatic, and non-sensitizing	Hypoallergenic, bacteriostatic, and non-sensitizing
	pH = 6.5 ± 0.75	pH = 6.5 ± 0.75
	Density (g/cm^3) = 0.983	Density (g/cm^3) = 0.99
	Very clear screen image with high viscosity and vacuum process. No rapid melting from high-viscosity gel. Viscosity: 100000-200000 cp	It has low viscosity. It melts immediately from low viscosity. Viscosity: 35000-45000 cp
	Boiling Point > 200°F	Boiling Point = 100°C
	Water soluble high polymer	Water soluble polymer
	No irritation	No irritation
PROCESS	It has very quick production process	Normal process
	Our product has a very soft bottle that provides ease of use.	It is made with a standard bottle
	Our production system is a closed-loop system so pollution of transmission is not in question. Products are manufactured very cleanly.	Standard process
	Konix® Ultrasound Gel is produced in a clean room with Hepa filters (1/100000 class)	Standard production area

	Konix® Ultrasound Gel is manufactured with high technology that includes a vacuum process. The product does not contain bubbles. This is important because bubbles can cancel the screen image.	Standard process
LABEL	Very clear information on label. The label is made with Polyethylene so that the label information is not deleted to quickly.	Standard label information
DESIGN	Bottle diameter designed according to the ultrasound device Bottle cap has been designed to easily open and close for single-handedness.	Conical cap
SAFETY	Konix® Ultrasound Gel's label contains all the safety signs (Latex free, PVC free, etc.)	Contains standard signs
ENVIRONMENT OF USE	Hospital	Hospital
TARGET POPULATION	Pediatric and adult	Pediatric and adult
ANATOMICAL SITE	Body (abdomen)	Body (abdomen)
USE	Multiple use	Multiple use
MATERIAL (PACKAGE)	Polyethylene	Polyethylene
PATIENT CONTACT MATERIALS	Probe	Probe
ENERGY TYPE	Only electricity for ultrasound device	Only electricity for ultrasound device

Non-clinical performance

Konix® Ultrasound Gel was evaluated for its acoustic performance. Results indicate that the acoustic properties of the gel:

1. are virtually identical to human skin, and
2. are virtually identical to other coupling gels commonly used today in the United States.

Finally, Konix Ultrasound Gel's acoustic properties are as follows:

Sound velocity (m/sec) at 30°C[1]	1,516
Density (kg/m^3) at 30°C	0.98 x 10^{-3}
Acoustic impedance (kg/m^2 sec) at 30°C	1.49
Attenuation coefficient as a function of frequency, a/f (dB/(cm-MHz)	< 0.05

Conclusions

The above-referenced comparisons of the technological and non-clinical performance characteristics indicate that the Konix® Ultrasound Gel is almost identical to its predicate and certainly substantially equivalent to it and other coupling gels commonly used in the United States today.

[1] The "longitudinal velocity" of skin is reported to be 1,518. The optimal average is 1,520. (See, e.g., Ogura, I., Kidikoro, T., Iinuma, K., Takahara, Y., Tanaka, K. and Matsuda, A. "Measurement of Acoustic Impedance of Skin" Ultrasound in Medicine, Vol. 4, RC 78.7, U4 A 5a, page 535 (1978).

The "Acoustic impendance" of skin is reported to be 1.6 kg/m^2 s. (See, Ogura (1978)).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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MAY 27 2011

Re: K101952
Trade Name: Konix®Ultrasound Gel
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: May 4, 2011
Received: May 6, 2011

Dear Mr. Scott:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

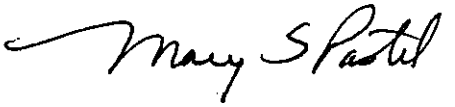
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K101952

Device Name: Konix® Ultrasound Gel

Indications for Use:

Konix® Ultrasound Gel is intended for general use as a nonsterile transmission media for acoustically coupling a transducer to a human body surface during external, 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101952