AUG 30 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is furnished in accordance with requirements detailed in 21 CFR 807.92.

1.

The assigned 510(k) number is K-121311

Submitter's Identification:
Cloverline International Pharma Services GmbH
Teinacher Strasse 49
Ludwigsburg, Germany D-71634

Correspondence:

Christina Bernstein
BB Medical Surgical, inc.
2670 Leavenworth Street
San Francisco, CA 94133
Tel: 415-450-0515
Email tina@bbmedicalsurgical.com

Date of submission 25 April 2012
Date of revised summary 31 July 2012,
second revision 15 August 2012.

2.

Device name:

Proprietary name: Thixo-Gel Ultrasound Spray®

A.Regulation Section: 21 CFR 892.1570 Diagnostic Ultrasound Transducer Accessory

B.Classification: Class II

C.Product Code: MUI

D.Panel: Radiology

3.

Intended Use:

Thixo-Gel Ultrasound Spray® is used as an ultrasound coupling medium for diagnostic and therapeutic procedures on external, intact skin for a short duration.

4.

Device Description:

Thixo-Gel Ultrasound Spray® is a colorless, thixotropic gel contained in a dispenser that allows it to be dispersed as a thin layer on external, intact skin.

5.

Substantial Equivalence Information:

A. Predicate device name: Aquasonic 100®
B. Predicate device K number: 802146
C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	THIXO-GEL ULTRASOUND SPRAY ®	AQUASONIC 100 ®
K-Number	121311	802146
Device Description	Ultrasound Couplant	Ultrasound Couplant
Acoustic Impedance	0.166 gm/cm^2	0.163 gm/cm^2
Density	1056 km/m^3	1012 km/m^3
Attenuation @ 10 MHz	1-2 dB/mm	1-2 dB/mm
Sound Velocity	1566 m/sec	1588 m/sec
Dispenser	250 ml nozzle spray bottle (single use)	250 ml squeeze bottle (refillable)

6.

Test Principle, Performance Characteristics:

FDA has not established special controls or performance standards for this device.

7.

Bench Top Testing:

Tests for biocompatibility were performed in accordance with ISO-10993.

Bacterial contamination retests were also performed on the subject device for shelf life testing.

Physical property comparison tests were performed on the submitted device and predicate.

8.

Conclusions:

Thixo-Gel Ultrasound Spray® is similar in intended use and technological characteristics to predicate devices reviewed used to couple ultrasound devices to skin. The device is similar with respect to indications for use and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Contraindications: Thixo-Gel Ultrasound Spray® is not for use with defibrillators.

Warnings and Precautions: The precautions are provided in the device labeling for Thixo-Gel Ultrasound Spray®. There is no warning associated with this device.

9.

Summary:

Description	Comparison with Predicate Device
Biocompatibility	Safe as Predicate Device
Performance Characteristics	Substantially equivalent
Intended Use	Substantially equivalent
Performance Tests	Not Required

The device Thixo-Gel Ultrasound Spray®, based on the information submitted in this 510(k) application has been demonstrated to be substantially equivalent to the predicate device AQUASONIC 100® (K-802146), manufactured by Parker Laboratories, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 30 2012

Cloverline International Pharma Services GmbH
% Ms. Christina Bernstein
US Agent
BB Medical Surgical, Inc.
2670 Leavenworth Street
SAN FRANCISCO CA 94133

Re: K121311
Trade/Device Name: Thixo-Gel Ultrasound Spray®
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: MUI
Dated: August 7, 2012
Received: August 7, 2012

Dear Ms. Bernstein:

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.

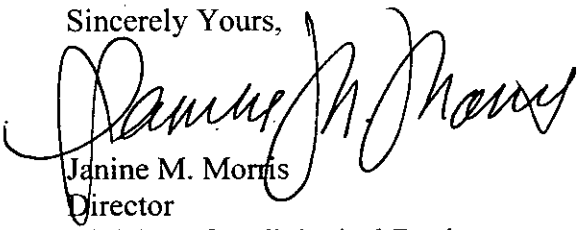
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
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): K-121311

Device Name: Thixo-Gel Ultrasound Spray®

Indications for Use:

Thixo-Gel Ultrasound Spray® is used as an ultrasound coupling medium for diagnostic and therapeutic procedures on external, intact skin for a short duration.

Prescription Use _Yes__ AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (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)

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

510(k) K121311

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