K102372

Chapter 05

PREMARKET NOTIFICATION
510(K) Summary

NOV - 3 2010

OBS Disposable Electrosurgical Pads, Solid (Model: GBS-Dm)

OBS Disposable Electrosurgical Pads, Split (Model: GBS-Db)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name:

JIANGMEN CITY XINHUI BAISHENG MEDICAL EQUIPMENT CO.,LTD

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Contact:	Mr. Chen Xi
E-mail:	renzheng@bs0750.com
Date	December 28, 2009

2.0 Proprietary Name: OBS Disposable Electrosurgical Pads, Solid (Model: GBS-Dm)
OBS Disposable Electrosurgical Pads, Split (Model: GBS-Db)

Common Name : Electrosurgical Pad

Regulation Number: 21 CFR 878.4400
Classification Name: Electrosurgical, cutting & coagulation & accessories
Classification: Class II
Product Code: GEI
Panel: General & Plastic Surgery

3.0 Predicate Device Information:

1) **Leonhard Lang GmbH**
Company Name: Leonhard Lang GmbH
Address: Archenweg 56 6010 Innsbruck Austria
Proprietary Name: Skintact® Cool Contact Electrosurgical Grounding Plates
It's 510(K) number is K030362

2) **ConMed Corporation**

Company Name: ConMed Corporation

Address: 310 Broad Street Utica, New York 13501

Proprietary Name: SureFit™ Dual Dispersive Electrode (410-2000)

It's 510(K) number is K002002

3) **Valleylab**

Company Name: Valleylab,INC.

Address: 5910 Longbow Drive Boulder CO 80301

Proprietary Name: PolyHesive II Patient Return Electrode(Mode E7506:solid,with cable.Model E7507:REM,with cable.Model E7509:REM,without cable)

It's 510(K) number is K861036

4.0 Device Description

OBS Disposable Electrosurgical Pads are disposable, non-sterile dispersive electrode with or without a pre-attached cord and available in a comprehensive range of shapes and sizes(adult and pediatric). OBS disposable electrosurgical pads, Solid (Model:GBS-Dm) are for use with generators that do not have a Contact Quality Monitoring System(CQMS).OBS disposable electrosurgical pads, Split (Model:GBS-Db) are for use with generators that have a Contact Quality Monitoring System(i.e. REM,ARM,NESSY etc.).

5.0 Indications for Use:

OBS Disposable Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System(CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS(i.e.REM,ARM,NESSY etc.).

6.0 Comparison to Predicate Devices

OBS Disposable Electrosurgical Pads have been carefully compared to legally marketed devices with respect to intended use, appearance, essential components, materials and performance specifications. They are similar in intended use, appearance, essential components, materials and performance specifications. Although they may differ from the predicate devices in color and shape, it won't affect safety and effectiveness of subject devices. In addition, performance and safety testing have been done to validate the performance and safety of the device.

7.0 Summary of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as below:

Electrical safety test, Electromagnetic compatibility test and Biocompatibility test have been done to demonstrate the safety and performance of subject devices. Tests was conducted on the OBS Disposable Electrosurgical Pads, model GBS-Db and GBS-Dm, in accordance with the "510(k) Guidance Document for General Surgical Electrosurgical Devices", which outlines safety and performance requirements. The test details as follow:

Safety test: FDA-Electrosurgical-GBS-Appendix-01 Safety and Performance Test
FDA-Electrosurgical-GBS-Appendix-05 Safety and Performance Test

Standard:1) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
2) IEC 60601-2-2- 2006, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment. (General Plastic Surgery/General Hospital)

Test result: For the Safety test, all the testing items pass the above standards, it demonstrates that the subject devices OBS Disposable Electrosurgical Pads, model GBS-Db and GBS-Dm, comply with the safety and performance requirements.

EMC test: FDA-Electrosurgical-GBS-Appendix-02 EMC Test Report
FDA-Electrosurgical-GBS-Appendix-06 EMC Test Report

Standard: 1) IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004). (General)

Test result: For the EMC test, the testing items Emission and Immunity, Harmonic Current Emissions, Voltage changes, Voltage Fluctuations and Flicker, pass the above standard, it demonstrates that the subject devices OBS Disposable Electrosurgical Pads, model GBS-Db and GBS-Dm, comply with the safety and performance requirements.

Biocompatibility test: FDA-Electrosurgical-GBS-Appendix-03 Biocompatibility Test

FDA-Electrosurgical-GBS-Appendix-07 Biocompatibility Test

Standard: 1) AAMI / ANSI / ISO 10993-1:2003, Biological evaluation of medical devices -- Part 1: Evaluation and testing. (Biocompatibility)

2) AAMI / ANSI / ISO 10993-5:1999, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)

3) AAMI / ANSI / ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity. (Biocompatibility)

4) AAMI / ANSI / ISO 10993-12:2007, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials. (Biocompatibility)

Test result: For the Biocompatibility test, the testing items Delayed Hypersensitivity, Skin Irritation and In Vitro Cytotoxicity, pass the above standard, the test result is no sensitization, no skin irritation and no cytotoxicity, it demonstrates that the subject devices OBS Disposable Electrosurgical Pads, both aged and unaged samples, comply with the safety and performance requirements.

Summary of test results:

Through the above Safety test, EMC test and Biocompatibility test, none of the testing items were demonstrated to violate the requirements of the above mentioned standards or result in any safety hazards.

8.0 Conclusions:

OBS Disposable Electrosurgical Pads, model GBS-Dm and GBS-Db, have been carefully compared to legal marketed predicated devices with respect to intended use, appearance, essential components, materials and performance specifications. They are similar in intended use, appearance, essential components, materials and performance specifications. Although they may differ from the predicate devices in color and shape, it won't affect safety and effectiveness of subject devices. And the Safety test, EMC test and Biocompatibility test have been done to validate the performance and safety of the subject device. The comparison, validation and test results presented in this 510k notification to the FDA show that the OBS Disposable Electrosurgical Pads, Solid (Model:GBS-Dm) and OBS Disposable Electrosurgical Pads, Split (Model:GBS-Db) are substantially equivalent to predicated devices and is safe and effective in their intended use.

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

Jiangmen City Xinhui Baisheng Medical Equipment Co., LTD
% Intertek Testing Services NA, Inc.
Mr. William J. Sammons
2307 E. Aurora Road Unit B7
Twinsburg, OH 44087

NOV - 3 2010

Re: K102372
Trade/Device Name: OBS Disposable Electrosurgical Pads, Solid (Model: GBS-Dm)
OBS Disposable Electrosurgical Pads, Split (Model: GBS-Db)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 15, 2010
Received: October 19, 2010

Dear Mr. Sammons:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102372

Chapter 04

PREMARKET NOTIFICATION

Indications for Use

NOV - 3 2010

510(k) Number (if known):

Device Name: OBS Disposable Electrosurgical Pads, Solid (Model: GBS-Dm)
OBS Disposable Electrosurgical Pads, Split (Model: GBS-Db)

Indications For Use:

OBS Disposable Electrosurgical Pads are Neutral Electrode which is also known as plate, plate electrode, passive, return, or dispersive electrode. They are indicated for use to adhere to the patient over the entire pad surface to complete an electrical circuit during electrosurgery between the electrosurgical generator, the active electrode and the patient. Solid Electrosurgical Pads are for use with generators that do not have a Contact Quality Monitoring System(CQMS). Split Electrosurgical Pads are for use with generators that have a CQMS(i.e.REM,ARM,NESSY etc.).

Prescription Use ___√___ **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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102372