K100527

1/3

510(K) SUMMARY

FEB - 2 2011

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. Submitter's Name: **Maxigen Bioteq INC.**

Address: 17, Wuchiuan 8th Rd., Wugu Shiang Taipei, Taiwan

Phone: + 886-2-2398-2345

Fax: + 886-2-5591-9522

Contact: Cinn-Jenn Wei/ President

2. Device Name :

Trade Name: **SurgiAid Collagen Wound Dressing**

Common Name: **Wound Dressing**

Classification name **Collagen Wound Dressing**

3. DEVICE CLASS **SurgiAid Collagen Wound Dressing** has been classified as
Regulatory Class: Unclassified
Product Code: KGN
Panel : General & Plastic Surgery

4. Predicate Device: The predicate device is the

- **SkinTemp** (K925545) marketed by **BIOCORE.**

5. Device Description: **SugiAid Collagen Wound Dressing** is white, porous, pliable and absorbable collagen wound dressings. It is fabricated by **fibrous collagen matrix** which is purified from bovine **Achilles** tendon. SugiAid is pliable and can be applied easily to clean wounds. The product is supplied in sterile, non-pyrogenic package, and is indicated for single use only.

6. Intended Use: **SurgiAid Collagen Wound Dressing** is intended for use in patients who have surgical wounds, donor sites/grafts podiatric wounds, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm."

K100927

2/3

7. Performance Summary:

The **SurgiAid Wound Dressing** has been subjected to extensive Non-clinical testing to assess the biocompatibility and the performance of the device.

The Biocompatibility Evaluations include: cytotoxicity, hemolysis , sensitization, intracutaneous reactivity, acute systemic toxicity , genotoxicity , implantation and pyrogenicity. That is, the **SurgiAid Wound Dressing** conforms to the requirements specified in ISO 10993-1:2009 series.

The Pre-clinical Benchtop Type Evaluations performed contain: Physical tests, Chemical tests, and Substantial Equivalent Comparisons, in order to demonstrate the substantial equivalence between the **SurgiAid Collagen Wound Dressing** and predicate device, including Purity (Collagen content), Endotoxin level (Pyrogen test), Pepsin resistance, Collagenase resistance & Rehydration Test ..... etc.

8. Substantial Equivalence Discussion

SugiAid Collagen Wound Dressing has the same general design with the predicate devices

Since the Applicant has selected Legally Marketed Devices

- **SkinTemp** (K925545) marketed by **BIOCORE.**

The has the following similarities to the predicate device in:

- having the same intended use.
- using similar operating principle,.
- using similar technological characteristics

In summary, the **SugiAid Collagen Wound Dressing** described in this submission is, in our opinion, substantially equivalent to the predicate device.

K100937

3/3

9. Conclusions:

The **SurgiAid Collagen Wound Dressing** has the same intended use and technological characteristics as the **SkinTemp** (K925545) marketed by **BIOCORE**. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **SurgiAid Collagen Wound Dressing** is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maxigen Biotech, Inc.
% Harvest Consulting Group
Ms. Jennifer Reich
2904 N. Boldt Avenue
Flagstaff, Arizona 86001

MAR 16 2011

Re: K100927
Trade/Device Name: SurgiAid Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 28, 2011
Received: January 31, 2011

Dear Ms. Reich:

This letter corrects our substantially equivalent letter of February 2, 2011.

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 (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 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.

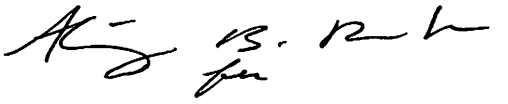
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Indications for Use

510(k) Number (if known): K100927

Device Name: **SurgiAid Collagen Wound Dressing**
Maxigen Biotech, Inc.

Indications for Use:

SurgiAid Collagen Wound Dressing is intended for use in patients who have surgical wounds, donor sites/grafts podiatric wounds, wound dehiscence, traumatic wounds, abrasions, lacerations, partial thickness burns or skin tears. SurgiAid Collagen Wound Dressing can be applied to wounds with depth less than 0.3 cm."

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100927