BSI bio-scaffold International Pte ltd

K080308

APR 14 2008

510(k) Summary in accordance with 21 CFR 807.92(c)

The 510(k) Summary of Safety and Effectiveness for Bioscaff™ Alvelac™ follows:

Device Name: Bioscaff™ Alvelac™

Type of 510(k) submission: Abbreviated

Date of Submission: February 1st, 2008

Manufacturer/510(k) Submitter:
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510(k) Contact:
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Director, Global Regulatory Affairs
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Italy

Tel: +39 06 578 2665
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Trade Name: Bioscaff™ Alvelac™

Common Name: Dental Bone Grafting Material

Classification Name: Bone Grafting Material

Regulation: 21 CFR 872.3930

Product Code: LYC

Predicate Devices:

1. Cytoplast™ Resorb
   Osteogenics Co
   3234 64th Street
   Lubbock, TX 79413
   USA

   K993610

2. Inion GTR™ Biodegradable Membrane
   Inion Ltd
   Laakarinkatu 2
   FIN-33520, Tampere
   Finland

   K033074

Device Description:

The Bioscaff™ Alvelac™ is a synthetic polymer scaffold synthesized from Poly (lactic-co-glycolic) acid (PLGA) and poly vinyl acetate (PVA). The scaffold is designed with macro channels and micropores for cell adhesion, as well as to provide the necessary space for bone and tissues to grow.

Intended Use:

A bioabsorbable implantable matrix intended for use as a space-making barrier in the treatment of periodontal defects and maxillofacial guided tissue regeneration procedures, including preservation and regeneration of alveolar bone height and volume, ridge and extraction site augmentation, sinus lifts, and treatment of associated cystic defects. It is also intended for use as a grafting material containment matrix.

Technological Characteristics:

The Bioscaff™ Alvelac™ uses PLGA with a monomer ratio of 85:15 (85% lactic acid and 15% glycolic acid), formed into one of a range of devices of different shapes and sizes. The matrix is approximately 30% PLGA, 70% air, with a pore size of 20-150 µm, suited to promoting bony in-growth, whilst retaining the necessary configuration, shape and strength for clinical use.

The predicate devices use similar biocompatible copolymers to produce bio-absorbable membranes or mesh that is used to provide space-making barriers after dental or maxillo-facial surgery, to provide temporary support during the tissue and bone regeneration process.

The different types of copolymer used result in different resorption rates, to suit the intended clinical objectives.

All three devices are supplied sterile for single use.

Performance Data:

The mechanical properties of the Bioscaff™ Alvelac™ have been determined to be suitable for the intended use. Animal studies have confirmed biocompatibility, resorption rate, and good bone formation.

Conclusions:

Based on the information contained within this submission, it is concluded that the Bioscaff™ Alvelac™ is substantially equivalent to the predicate devices already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2008

Bio-Scaffold International Pte Limited
C/O Mr. Roger Gray
Director, Global Regulatory Affairs
Donawa Consulting
Piazza Albania, 10
00153 Rome
ITALY

Re: K080308
Trade/Device Name: Bio-Scaffold Bioscaff Alvelac Resorbable Scaffold
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: LYC and NPK
Dated: February 1, 2008
Received: February 5, 2008

Dear Mr. Gray:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A

Indications for Use Statement

See overleaf for Indications for Use Statement in accordance with the format requested by FDA.

Indications for Use

510(k) Number (if known): ~~Not known~~ K080308

Device Name: Bio-Scaffold Bioscaff Alvelac Resorbable Scaffold

Indications for Use: Bio-Scaffold Bioscaff Alvelac Scaffold is a bioabsorbable implantable matrix intended for use as a space-making barrier in the treatment of periodontal defects and maxillofacial guided tissue regeneration procedures, including preservation and conservation of alveolar bone height and volume, ridge and extraction site augmentation, sinus lifts, and treatment of associated cystic defects. It is also intended for use as a grafting material containment matrix.

Prescription Use (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080308