JAN 1 5 2004

K033815

**510(k) Summary**

**BIO-OSS®**

**BIO-OSS® Blocks**

**BIO-OSS® Collagen**

## 1. SPONSOR

Geistlich Pharma Ag
Bahnhofstrasse 40
CH-6110 Wolhusen
SWITZERLAND

Contact Person: Dr. Susana Wäsch, 011-41-41-49-25-630
Date Prepared: December 5, 2003

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | BIO-OSS®, BIO-OSS® Blocks, BIO-OSS® Collagen |
| Common/Usual Name: | Anorganic Bovine Bone Filling Material |
| Classification Name: | Bone Filling Material |

## 3. PREDICATE DEVICES

BIO-OSS® (K871773, K952617, and K970321)
BIO-OSS® Blocks (K920508, K952618, and K970569)
BIO-OSS® Collagen (K974399)

## 4. INTENDED USE

BIO-OSS®, BIO-OSS Blocks and BIO-OSS® Collagen are recommended for:

- Filling of large oral and maxillofacial intra-osseous cavities

## 5. DEVICE DESCRIPTION

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are natural non-antigenic, porous bone mineral matrixes. They are produced by removal of all organic components from bovine bone. Due to its natural structure, BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are physically and chemically comparable to the mineralized matrix of human bone. It is available as cortical granules and blocks.

## 6. BASIS FOR SUBSTANTIAL EQUIVALENCE

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are substantially equivalent to Geistlich's existing products, BIO-OSS® Anorganic Bovine Bone (K871773, K952617, and K970321), BIO-OSS® Blocks (K920508, K952618, and K970569), and BIO-OSS®

Collagen (K974399). The only difference between the new products and the products previously cleared is that an alternative geographic source for the bovine bone is proposed to be added - Australia. The current source of bone is the United States. The European Union, in its Report on the Assessment of the Geographical BSE-risk of Australia, found Australia to have a level I Geographical BSE-risk ("GBR") - which means that it is highly unlikely that there is the presence of one or more cattle clinically or pre-clinically infected with the BSE agent in Australia. The United States has a level II GBR. It should be noted that Australia is not on the U.S. Department of Agriculture's list of countries affected with BSE. See 9 C.F.R. § 94.18. The company has performed a Risk Assessment per FDA Guidance to address traceability and pedigree of the herds. Therefore, using an alternative source of bovine bone will not negatively impact the products' safety or effectiveness.

With regard to the safety and effectiveness of the anorganic bovine bone used in BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen Geistlich incorporates by reference all of the information on the use of BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen in the above referenced 510(k) submissions.

BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen, as proposed to be sourced are substantially equivalent to the existing BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen products, in substance, function and intended use.

Based on the foregoing, Geistlich believes that the information and data herein submitted demonstrates not only that these versions of BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen are substantially equivalent to existing BIO-OSS®, BIO-OSS® Blocks, and BIO-OSS® Collagen products but also that these products have been shown to be safe and effective for the labeled indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

Geistlich-Pharma Ag
C/O Mr. Peter S. Reichertz
Sonnenschein Nath & Rosenthall LLP
1301 K Street NW
Suite 600, East Tower
Washington, D.C. 20005

Re: K033815
Trade/Device Name: BIO-OSS Granules, BIO-OSS Blocks and BIO-OSS Collagen
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: NPM
Dated: December 8, 2003
Received: December 12, 2003

Dear Mr. Reichertz:

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.

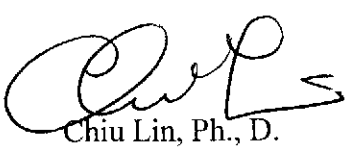
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.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

K033815

# Indications for Use

510(k) Number (if known): K033815

Device Name: BIO-OSS Granules, BIO-OSS Blocks and BIO-OSS Collagen

Indications for Use:

Augmentation or reconstructive treatment of alveolar ridge
Filling of periodontal defects
Filing of defects after root resection, apicoectomy, and cystectomy
Filing of extraction sockets to enhance preservation of the alveolar ridge
Elevation of maxillary sinus floor

Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).

Filing of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K033815