DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Mr Keith Barritt, Esq
Fish and Richardson, P.C.
1425 K Street, N. W.
Washington, D. C. 20005

Re: K040783
Trade/Device Name: FOUNDATION Wound Covering Material
Regulation Name: Bone Void Filler
Regulatory Class: Unclassified
Product Code: LYC
Dated: March 25, 2004
Received: March 26, 2004

Dear Mr. Barritt:

This letter corrects our substantially equivalent letter of October 13, 2004, regarding FDA's clearance of K040783, using a version of the FOUNDATION Indications for Use Statement that was not the latest revision of that statement. The correct Indications for Use Statement is enclosed.

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 use in filling extraction sockets, 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.

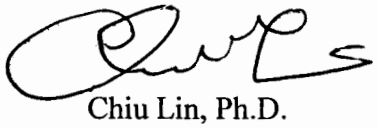
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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" (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

K040783

510(k) Number (if known):
Device Name: FOUNDATION Bone Filling Augmentation Material
Indications For Use:

The FOUNDATION device is a collagen-based bone filling augmentation material for use in the filling of extraction sockets.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

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

510(k) Number: K040783

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K040783

OCT 13 2004

510(k) SUMMARY

Terumo Corporation
FOUNDATION Bone Filling Augmentation Material
510(k) Premarket Notification

Name of Device and Name/Address of Sponsor

Trade or Proprietary Name: FOUNDATION

Common Name: wound covering material

Classification Name: bone filling augmentation material

Product Code : LYC (unclassified)

Terumo Corporation
44-1, 2 chome
Hatagaya, Shibuya-ku
Tokyo 151-0072
Japan

Contact Person: Mr. Yoshiaki Nagura
Date Prepared: May 26, 2003

Intended Use

The FOUNDATION device is a collagen-based bone filling augmentation material for use in the filling of extraction sockets with oral maxillofacial defects.

Technological Characteristics and Substantial Equivalence

The FOUNDATION device is a sponge-like absorbable natural collagen plug designed to be used as a bone filling material for dental bone defects. The device consists of approximately 85-95% Type I collagen and approximately 5-15% Type III collagen from bovine dermis collagen sources in the United States.

The FOUNDATION device is manufactured in both bullet-shape and in sheets. The device comes in a heat-sealed aluminum package.

Atelocollagen (pepsin solubilized collagen) is purchased from a raw material supplier. Testing is performed to ensure that the telo-peptide has been removed. Protein, excluding collagen, and fat are removed during the extraction process from bovine dermis to atelocollagen at the raw materials supplier's facility. To control antigenicity throughout the manufacturing process, tyrosine moiety is controlled at less than 3/1000. All of the manufacturing of the FOUNDATION device takes place in a "clean room."

The FOUNDATION device is packaged into individual packages and heat-sealed. Quality testing before shipping is performed on the finished devices. The product is physically tested for appearance. Cross-linking is verified by testing to ensure the product maintains its operating characteristics. Sterility tests are also performed.

The FOUNDATION device was approved by the Japanese Ministry of Health, Welfare and Labor as the TERUPLUG on July 7, 1997 for the following indications: (1) to stop bleeding after an odontectomy; (2) to cover the surface of a wound created by an odontectomy to prevent contamination and infection of the wound; (3) to accelerate granulation formation at the site of the odontectomy; and (4) to relieve pain at the wound site due to wound coverage.

The FOUNDATION device is substantially equivalent for purposes of the FDA's medical device regulations to BIO-OSS COLLAGEN, which is approved for the filling of extraction sockets to enhance the preservation of the alveolar ridge (K#974399). The FOUNDATION device has the same general intended use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device. Although there are some difference in the characteristics of the FOUNDATION device and the predicate device, such as sponge configuration vs. granular configuration, these differences do not raise new questions of safety or efficacy.

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