K111087

Section 5.0
510(k) Summary

NOV 2 9 2011

Submitter Name:	Olympus Terumo Biomaterials Corporation
Submitter Address:	Shinjuku Monolith 3-1 Nishi-Shinjuku 2-chome Shinjuku-ku Tokyo, Japan 163-0914
Contact Person:	Laura Storms-Tyler, US Agent
Telephone Number for US Agent:	484-896-5688
Date Prepared:	August 25, 2011
Device Trade Name:	FOUNDATION
Classification Name and Number:	Bone grafting material 21 CFR 872.3930
Class:	2
Product Code	LYC
Common Name:	Bone grafting material, synthetic
Predicate Device:	FOUNDATION, Terumo Corporation, K040783
Statement of Intended Use:	The FOUNDATION device is a collagen-based bone filling augmentation material for use in filling of extraction sockets.
Device Description, Summary of Technological Characteristics	The FOUNDATION bone filler device is a sponge-like absorbable natural collagen plug designed to be used as indicated. FOUNDATION consists of approximately 85-95% Type I collagen and approximately 5-15% Type III collagen from bovine dermis.
Comparison to the Predicate Device	The FOUNDATION is available as a bullet shape in three sizes (in mm: 8x15, 8x25, 15x25) and a sheet type in two sizes (mm: 25x25 and 50x25). The device is provided sterile, for single use in a heat-sealed aluminum package. The FOUNDATION is substantially equivalent to its parent FOUNDATION predicate device in the raw material source and type of collagen, in device design, and in product forms and sizes.
Conclusion regarding Substantial Equivalence	The difference in the country source for the bovine raw material is the purpose for submitting this 510(k). Appropriate controls and validations assure there is no effect on the safety, performance, and thus substantial equivalence of the new FOUNDATION compared to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Olympus Terumo Biomaterials Corporation
C/O Ms. Patsy J. Trisler
Regulatory Consultant
Trisler Consulting
5600 Wisonsin Avenue, # 509
Chevy Chase, Maryland 20815

NOV 2 9 2011

Re: K111087
Trade/Device Name: Foundation
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: October 24, 2011
Received: October 27, 2011

Dear Ms. Trisler:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K11 1087

Device Name: Foundation

Indications for Use:

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

Prescription Use ___x___ (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)

(Posted November 13, 2003)

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

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