

JAN 27 2000

K993784

510(k) summary
(As Required by Section 807.92 (c))

1. Submitter

Name: Unicare Biomedical, Inc.
Address: 25951 La Cuesta Avenue, Laguna Hills, CA 92653
Contact: Stan Yang, 949-362-1772
Date: November 5, 1999

2. Device Name

Trade Name: Unigraft
Common Name: Synthetic bone graft material
Classification Name: Endosseous implant for bone filling and augmentation
Device Classification: Class III

3. Predicate Devices

PerioGlas®, BioGran® and others

4. Device Description

Unigraft is a synthetic bioactive glass material for use in the repair of oral defects, including periodontal defects, extraction sites and augmentation of the alveolar ridge. It is manufactured as irregular shaped synthetic granules, sized at 200-420 microns.

The bioactive glass (45S5 Bioglass) used in Unigraft is one of the most extensively studied bioactive glass compositions, which has been shown to bond to bone as well as soft tissue. The same material is used in legally marketed devices, including BioGran® and PerioGlas®. When implanted in the living tissue, the material undergoes a time dependent surface modification. The surface reaction results in the formation of a calcium phosphate layer, which is equivalent in composition and structure to the hydroxyapatite found in bone minerals. The biological apatite layer of the granules provides an osteo-conductive scaffold for the generation of new osseous tissue.

5. Comparison with Predicate Devices

The Unigraft device is substantially equivalent to devices currently in US commercial distribution, which are classified as endosseous implant for bone filling and augmentation. Examples of such products include PerioGlas®, BioGran® and OsteoGraf. These products are made of bioactive ceramic materials with similar performance.

6. Device Testing

The Unigraft device was evaluated comparatively against a predicate device using a variety of test methods. The results of these tests demonstrate that the Unigraft device is substantially equivalent to a predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

Stan Yang, Ph.D.
Unicare Biomedical, Incorporated
25951 La Cuesta Avenue
Laguna Hills, CA 92653

Re: K993784
Trade Name: Unigraft
Regulatory Class: Unclassified
Product Code: LYC
Dated: November 5, 1999
Received: November 8, 1999

Dear Dr. Yang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993784

510(K) NUMBER: K99-3784

DEVICE NAME: UNIGRAFT

INDICATIONS FOR USE:

For the repair of periodontal infrabony defects, extraction site and augmentation of the alveolar ridge

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____
(Optional Format 1-2-96)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993784