

K040980

JUL 14 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of ALLOMATRIX® C Putty, ALLOMATRIX® Custom Putty and ALLOMATRIX® DR Putty.

Submitted By: **Wright Medical Technology, Inc.**

Date: April 12, 2004

Contact Person: **Roger D. Brown**
Sr. Director, Clinical, Regulatory & Reimbursement

Proprietary Name: **ALLOMATRIX® C Putty, ALLOMATRIX® Custom Putty and ALLOMATRIX® DR Putty**

Common Name: Bone Void Filler

Classification Name and Reference: Filler, Calcium Sulfate Preformed Pellets – Class II, 888.3045

Device Product Code and Panel Code: Orthopedics/MQV

DEVICE INFORMATION

A. INTENDED USE

ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR Putty Products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR Putty Products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

B. DEVICE DESCRIPTION

ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR Putty Products come in the form of a kit with a premeasured powder and CBM chips, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR Putty Products were found to be substantially equivalent to the predicate devices. The safety and effectiveness of ALLOMATRIX® C, ALLOMATRIX® Custom and ALLOMATRIX® DR Putty Products is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

Osteoinductivity Potential

The DBM incorporated into the ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putty Products is assayed *in vitro* for its osteoinductive potential. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductivity index).¹ Results from the bioassay were correlated with results from implantation of DBM into athymic rat muscle², which demonstrated a correlation coefficient of 0.850 ($p < 0.0005$)¹ and accurately predicted the *in vivo* osteoinductivity of 99 of 101 donor lots. Additionally, clinical results using DBM with >0.20 and ≤ 0.20 demonstrated a significant difference in healing as evaluated by radiography, 92% and 33% healing, respectively.³

Each lot of DBM incorporated into ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putties is evaluated *in vitro* using a surrogate cell-based assay¹. The bioassay measures the proliferation of Saos human osteosarcoma cells in the presence of human DBM compared to positive and negative controls (osteoinductivity index)¹. Results from this bioassay were correlated to the athymic rat model² and to clinical results of assayed DBM alone³. Testing each lot of DBM with this cell-based bioassay¹ assures that only DBM with osteoinductive potential is used in the ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putties. The combination of DBM, CBM and binding medium has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in vitro* bioassay¹, will correlate with human clinical performance of ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putties.

- 1 Wilkins, R.M. (1999) Clinical Effectiveness of Demineralized Bone Matrix Assayed in Human Cell Culture, *Advances in Tissue Banking*, 3:113-124
- 2 Lindholm TS, Urist MR. A quantitative analysis of new bone formation by induction in composite grafts of bone marrow and bone matrix, *Clin Orthop* 1980 Jul-Aug;(150):288-300.
Note: The product is considered osteoinductive if one specimen (explant) contains new bone (i.e. bone occupied with lamellae), cartilage, and/or chondrocytes.
- 3 Data on file at Wright Medical Technology, Inc.

Viral Inactivation Potential

The method for processing the DBM and CBM contained in the ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putty Products was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes, and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses. The CBM processing methods were determined to provide some viral inactivation potential for a wide range of viruses. In comparison, the CBM processing methods provided less viral inactivation potential than the DBM processing methods; therefore, the risk for disease transmission from the CBM component is greater than the DBM component. However, the risk of disease transmission for these components remains low due to the multiple safeguards employed, i.e., donor selection, laboratory testing, and material processing.

Product Performance Testing

Evaluation of clinical performance was evaluated by a comparison of radiographic outcomes and the adverse event profiles compared to the predicate devices. There were no significant differences in the radiographic outcomes or adverse event profiles of the ALLOMATRIX[®] C, ALLOMATRIX[®] Custom and ALLOMATRIX[®] DR Putty Products and the predicate devices.

Performance of DBM putty formulations that included varying amounts of CBM were evaluated in a canine model by radiographic and histological methods.



JUL 14 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Roger D. Brown
Director, Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K040980
Allomatrix C, Allomatrix Custom and Allomatrix DR Putty Products
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: April 14, 2004
Received: April 15, 2004

Dear Mr. Brown:

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.

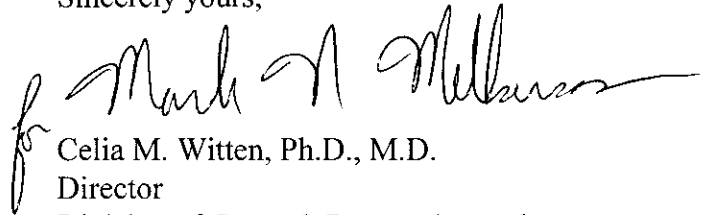
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 594-4659. 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style and is positioned to the right of the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K 040980

Device Name: ALLOMATRIX[®] C Putty, ALLOMATRIX[®] Custom Putty and
ALLOMATRIX[®] DR Putty

Indications for Use:

ALLOMATRIX[®] C Putty, ALLOMATRIX[®] Custom Putty and ALLOMATRIX[®] DR Putty are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX[®] C Putty, ALLOMATRIX[®] Custom Putty and ALLOMATRIX[®] DR Putty are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

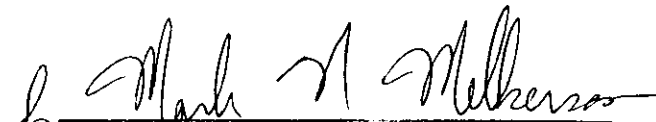
Prescription Use X
(Per21 CFR 801.109)

OR

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

(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 General, Restorative,
and Neurological Devices**

510(k) Number K 040980