

K973704

**BioGeneration™, Inc.**

APR - 3 1998  
9160 Highway 64, Suite 12  
Arlington, TN 38002  
Phone: (901) 380-9411  
Fax: (901) 389-8412

**510(K) SUMMARY**

**(As required by section 21 CFR 807.92(c))**

<b>Submitter's name:</b>	BioGeneration
<b>Submitter's address:</b>	9160 Highway 64, Suite 12, Arlington, TN 38002
<b>Submitter's telephone number:</b>	(901) 380-9411
<b>Contact Person:</b>	Bernard F. Grisoni, Ph.D
<b>Submission date:</b>	March 23, 1998
<b>Trade Name:</b>	ProFusion™ Bone Graft Substitute (subject to change)
<b>Common Name:</b>	Calcium Sulfate
<b>Classification Name:</b>	Unknown
<b>Legally marketed predicate device:</b>	Wright Plaster of Paris Pellets, also named Osteoset® Pellets (Wright Medical Technology)

**Device description:**

ProFusion™ implants are made of medical grade calcium sulfate and stearic acid (as processing aid). They are provided sterile for single use. The implants are non-pyrogenic, biodegradable, radiopaque and resorbed in approximately 30-60 days, when used according to labeling.

**Indications for use:**

The ProFusion™ implants are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The implant is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bony cavities may be surgically created or the result of traumatic injury. The implant provides a bone graft substitute that resorbs and is replaced with bone during the healing process. Because the implant is biodegradable and biocompatible, it may be used at an infected site.

**Technological characteristics:**

□ ProFusion devices have the equivalent technological characteristics (i.e. chemical composition, and dissolution rate performance) to the predicate device.

**Performance data:**

□ Testing demonstrated that the ProFusion devices have equivalent dissolution, mechanical and mass to volume ratio characteristics to the predicate device. Testing indicated that the product is non-pyrogenic.

**Basis for substantial equivalence:**

The ProFusion devices are safe and effective because they are equivalent to the predicate device in terms of chemical composition, indication of use, and product performances.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR - 3 1998

Bernard Grisoni, Ph.D.  
Technical Service Director and Owner  
BioGeneration  
9160 Highway 64, Suite 12  
Arlington, Tennessee 38002

Re: K973704  
Trade Name: ProFusion™ Bone Graft Substitute  
Regulatory Class: Unclassified  
Product Code: MQV  
Dated: January 27, 1998  
Received: January 29, 1998

Dear Dr. Grisoni:

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.

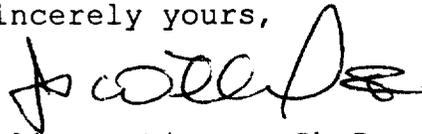
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 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.

Page 2 - Bernard Grisoni, Ph.D.

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) 594-4659. 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,

  
fm Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number: K973704

Device Name: ProFusion

Indication For Use:

The ProFusion™ implants are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The implant is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bony cavities may be surgically created or the result of traumatic injury. The implant provides a bone graft substitute that resorbs and is replaced with bone during the healing process. Because the implant is biodegradable and biocompatible, it may be used at an infected site.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973704

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)