This summary of 510k safety and effectiveness information being submitting in accordance with the requirement of SMDA and 21 CFR 807.92

1. Submitted by:

Submitter's Name	Biogennix, Inc
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Contact:	Edwin Clayton Shors

JUL 29 2010

2. Device Name:

Trade Name:	Biogennix RPC
Common Name:	Bone Void Filler
Classification Name:	Filler, bone void, calcium compound

3. Device Cass

Regulatory Class	II
Product Code	MQV
Panel	Orthopedic
Regulation Number:	21CFR 888.3045

4. Predicate Device: Pro Osteon 500R (K990131), marketed by Interpore Cross

5. Device Description: Biogennix RPC is an osteoconductive, open cell, resorbable ceramic. The ceramic is a composite of calcium salts. The open pores and porosity provide space and structure for bone and vascular ingrowth. The calcium salts resorb over time. The product is available in block and granular forms.

6. Intended Use: Biogennix RPC is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Biogennix RPC is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Biogennix RPC bone void filler may be used as a bone graft extender for posterolateral spine fusion when mixed in a one to one ratio with autogenous bone graft. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

7. Performance Summary: Comparative testing consistent with Class II Special Control Guidance Document: Resorbable Calcium Salt Bone Void filler Device: Guidance for Industry and FDA Staff (dated June 2, 2003) has been submitted to show that the Biogennix RPC is substantially equivalent to the predicate dice. Studies included x-ray diffraction, FTIR, IPS-MS, biomechanical, morphometry, in vitro dissolution, biocompatibility, and animal implantation in long bone defects and posterolateral spine. These studies demonstrated

that Biogennix RPC performed substantially equivalent to the predicate device. In addition, the device conforms to applicable standards , including ISO 10993 series: Biological evaluation of medical devices, ANSVAAMI/ISO 11137 Sterilization of Health Care Products for Radiation Sterilization

8. Conclusions: Biogennix RPC has the same intended use and technological characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrated that any differences in their technologic characteristics do not raise any new questions of safely or effectiveness. Thus, Biogennix RPC is substantial equivalent to the predicate device.

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

Biogennix, LLC
% Mr. Edwin C. Shors
President
19200 Von Karman Avenue – Suite 400
Irvine, California 92612

JUL 29 2010

Re: K093342
Trade/Device Name: Biogennix RPC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 13, 2010
Received: July 14, 2010

Dear Mr. Shors:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093342

Indication for Use Statement

JUL 29 2010

510K NUMBER K093342:

DEVICE NAME: Biogennix RPC

INDICATION FOR USE

Biogennix RPC is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Biogennix RPC is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the home. Biogennix PRC may be used as a bone graft extender in posterolateral spine fusion when mixed in a one to one ratio with autogenous bone graft. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __x___	AND/OR	Over the Counter Use _____
(Part 21 CFR 801 Subpart D		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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093342