510(K) SUMMARY

MAY 2 0 2014

Submitted on behalf of:

Company Name:	**BIOGENNIX, LLC**
Address:	**18011 Sky Park Circle, Ste M** **Irvine, CA 92614**
Telephone:	**949-253-0094**
Fax:	**949-266-5800**
by:	Elaine Duncan, M.S.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082
Telephone:	715-549-6035
Fax:	715-549-5380

CONTACT PERSON:	Elaine Duncan
DATE PREPARED:	May 12, 2014
TRADE NAME:	osteoSPAN Morpheus
COMMON NAME:	bone void filler
CLASSIFICATION NAME:	21 CFR 888.3045; Resorbable calcium salt bone void-filler device
PRO CODE:	MQV

DESCRIPTION of the DEVICE:

osteoSPAN Morpheus is a moldable, osteoconductive bone graft substitute composed of 1-2mm osteoSPAN granules suspended in a resorbable organic binder. The osteoSPAN granules used in **osteoSPAN Morpheus** are a composite of calcium carbonate with a thin calcium phosphate layer, in the form of hydroxyapatite, coating on all the surfaces of the interconnected porosity. The interconnected pores are approximately 500 microns in diameter and occupy approximately 65% of the volume. The biocompatible, organic binder facilitates placement and containment of the implant and is rapidly resorbed in-situ, leaving behind the osteoSPAN granules without affecting their osteoconductive or resorbable properties.

INDICATIONS FOR USE:

BIOGENNIX osteoSPAN Morpheus is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated 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

510(k) Summary-Continued

from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

SUMMARY of HOW TECHNOLOGICAL CHARACTERISTICS COMPARE:

Product	Calcium Salt	Granule Size	Porosity	Polymer Binder	Osteo-conductive
osteoSPAN Morpheus	Calcium carbonate/ calcium phosphate composite	1-2mm	65%	Yes	Yes
osteoSPAN (K093342)	Calcium carbonate/ calcium phosphate composite	1-4mm	65%	No	Yes
Actifuse ABX (K071206)	Silicate substituted calcium phosphate	1-2mm	80%	Yes	Yes

CONCLUSION FROM TESTING:

Chemical and physical testing confirmed acceptable findings and were consistent with prior osteoSPAN predicate device qualifications. Biogennix **osteoSPAN Morpheus** was thoroughly evaluated for biocompatibility in accordance with ISO 10993 appropriate parts and for performance, through multiple non-clinical in-vivo and ex-vivo studies. These studies conclusively demonstrate that **osteoSPAN Morpheus** is safe and performs as well as the primary predicate: osteoSPAN granules and like the material-reference: Actifuse ABX E-Z Fil Putty.

SUBSTANTIALLY EQUIVALENT TO:

The contents of this submission have demonstrated that **osteoSPAN Morpheus** is substantially equivalent to Biogennix osteoSPAN granules (primary predicate) (K093342) and to the material-reference predicate: Actifuse ABX E-Z-fil Putty (K071206) manufactured by Apatech, Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 20, 2014

Biogennix, LLC
% Ms. Elaine Duncan
President
Paladin Medical℠, Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K132377
Trade/Device Name: osteoSPAN Morpheus
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: April 11, 2014
Received: April 14, 2014

Dear Ms. Duncan:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132377

Device Name

osteoSPAN Morpheus

Indications for Use *(Describe)*

BIOGENNIX osteoSPAN Morpheus is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated 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. The product provides bone void filler that resorbs and is replaced with bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -A

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

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