July 14, 2016

Shefабone Incorporated
% Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K153230
  Trade/Device Name: ShefaBone SCPC Resorbable Bone Graft
  Regulation Number: 21 CFR 872.3930
  Regulation Name: Bone Grafting Material
  Regulatory Class: Class II
  Product Code: LYC
  Dated: June 7, 2016
  Received: June 8, 2016

Dear Elaine 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" (21 CFR 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,

Michael J. Ryan -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
ShefaBone SCPC Resorbable Bone Graft, is a silica-calcium phosphate composite, synthetic bone graft material for use in oral, dental intraosseous, and maxillofacial bone defects. Typical uses include:

- Periodontal / infrabony defects
- Ridge augmentation (sinusotomy, osteotomy, cystectomy)
- Extraction sites (ridge maintenance/augmentation, implant preparation/placement)
- Sinus lifts
- Cystic cavities
- Oral and maxillofacial augmentation

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)
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."

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(K) SUMMARY

Submitted on behalf of:
Shefabone Incorporated
c/o Ahmed El-Ghannam
President
9016 Cliff Cameron Drive, Ste 201
Charlotte, NC 28269

by:  Elaine Duncan, M.S.M.E., RAC (CONTACT PERSON)
President, Paladin Medical, Inc.
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Stillwater, MN 55082
Telephone:  715-549-6035
Fax:  715-549-5380

DATE PREPARED:  July 6, 2016

TRADE NAME:  ShefaBone SCPC Resorbable Bone Graft
COMMON NAME:  Bone void filler
CLASSIFICATION NAME:  Bone Grafting Material
PRO CODE:  LYC
REGULATION NUMBER:  872.3930

DESCRIPTION of the DEVICE:
ShefaBone SCPC is a synthetic resorbable osteoconductive bone graft composed of silicon oxide, phosphorous oxide, sodium oxide, and calcium oxide. The SCPC device is in a granules form. The SCPC particles are porous and uniform in density and composition. The particles are packaged in a glass vial, sealed in aluminum sterilization pouch, and Gama sterilized.

INDICATIONS FOR USE:
ShefaBone SCPC Resorbable Bioactive Bone Graft, is a silica-calcium phosphate composite, synthetic bone graft material for use in oral, dental intraosseous, and maxillofacial bone defects. Typical uses include:
• Periodontal / infrabony defects
• Ridge augmentation (sinusotomy, osteotomy, cystectomy)
• Extraction sites (ridge maintenance/augmentation, implant preparation/placement)
• Sinus lifts
• Cystic cavities
• Oral and maxillofacial augmentation

SUBSTANTIAL EQUIVALENCE:

Comparison of Differences of Indication for Use to (Primary) Predicate: Perioglass is a dense (non-porous) device indicated for use with bone graft extenders (such as demineralized bone), in addition to use as a bone graft alone. In contrast, SCPC granules are highly porous with high surface area available for bone formation. Animal performance testing demonstrated that the SCPC particle porosity enabled sufficient bone formation to augment the alveolar ridge after tooth extraction. Therefore, SCPC can be used in the same intended way as Perioglass, without bone extender materials, and it thus substantially equivalent to Perioglass for the same indication for use.

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<thead>
<tr>
<th>Parameters</th>
<th>Novabone—PRIMARY PREDICATE</th>
<th>SHEFABONE (SCPC)</th>
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<tr>
<td>510(k) #</td>
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<td>Classification &amp; ProCode</td>
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<td>Intended Use</td>
<td>Bone void filler</td>
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| Indication for Use  | PerioGlas - BioGlass Bone Graft Particulate is indicated to be packed into bony voids or gaps to fill and/or augment oral, dental intraosseous, and cranio-facial defects. These defects may include: periodontal/infrabony defects; | ShefaBone SCPC Resorbable Bioactive Bone Graft, is a silica-calcium phosphate composite, synthetic bone graft material for use in oral, dental intraosseous, and maxillofacial bone defects. Typical uses include:  
  • Periodontal / infrabony defects |
In addition, Shefabone SCPC is equivalent to aspects of the Reference Predicate K033611: Calcigen-NaP Bone filler. Calcigen NaP Bone void filler is made of calcium sodium phosphate cement that is crystalline material. The main component (84%) of SCPC granules is also crystalline sodium calcium phosphate. Both SCPC and Calcigen are resorbable bone grafts used to fill bone defects or cavities. Both SCPC granules and Calcigen bone cement are radiopaque and will be visible under X-ray to ensure that the bone void has been completely filled. The technological differences are that Calcigen is a calcium sodium phosphate cement. It is provided to the dentists or surgeons as two separate components in pre-measured quantities of powder and setting solution. The two components (powder and setting solution) are mixed together intra-operatively to form a thick, moldable paste made of NaCaPO4 that is then applied to the bone void or defect. After application, the Calcigen NaCaPO4 hardens and become porous solid block inside the bone defect. SCPC offers a sodium calcium phosphate as one component solid porous ceramic granules ready for implantation (not two components as calcigen). The presence of the sodium calcium phosphate phase in the form of solid granules instead of paste does not pose any new risks. In SCPC, the presence of minor silica phase in the sodium calcium phosphate does not pose any new risks. The silica (SiO2) is the main component (45%) of bioactive glass (Perioglass or Novabone).

**SUMMARY of TESTING/ BASIS of SUBSTANTIAL EQUIVALENCE:**

Gamma sterilization, package integrity and shelf-life stability testing were provided. Biocompatibility testing has been conducted in accordance with ISO 10993, Parts 1, 5, 12, and 14. Testing included FTIR analysis to demonstrate equivalence and XRD analysis of the phase composition before and after gamma sterilization. SEM and Energy Dispersive X-ray analysis was used to characterize elemental composition. The particle size distribution was analyzed and the SEM morphology of the SCPC particles was provided. Testing using mercury intrusion porosity measurements and gas adsorption BET surface area measurements were made. SCPC Dissolution extract in physiological solution was determined. Results from a 16 week pre-clinical study demonstrated that SCPC is a suitable graft material to augment the alveolar ridge after tooth extraction.

**CONCLUSION:**

Based upon a) comparative analysis to primary and reference predicates and b) from the results of the nonclinical studies, Shefabone SCPS is substantially equivalent to the primary predicate device.