



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2016

Shefabone 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

Indications for Use

510(k) Number (if known)

K153230

Device Name

ShefaBone SCPC Resorbable Bone Graft

Indications for Use (Describe)

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

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)

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

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“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**

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REGULATION NUMBER:

ShefaBone SCPC Resorbable Bone Graft

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872.3930

DESCRIPTION of the DEVICE:

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INDICATIONS FOR USE:

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SUBSTANTIAL EQUIVALENCE:

Comparison of Differences of Indication for Use to (Primary) Predicate: Ú|·æ^} |æ·Á Ááá^· ^Á Ç| | È| | | ·Dæçá| Á áæç| áÁ| Á·^Á á@æ| } ^Á| æç| çç| } á·Á Ç· & Çæ Áá^ } á| çæ^áá| } ^ÈÁ Ááááá } Á Á ·^Áæ Ááá| } ^Á| æç| } ^ÈÖ Ç| } çæ ÈÁÜÖÜÖÁ| á } ^·Áæ Ááá| Ç· Á| | | ·^Á á@Ç· Ç· | æ^Áæ^æç| æáæ| Á| Á Á à| } ^Á| | { æá } ÈÖÈ ç æ| ^| | { æ & Á· ç· Áá| | } ·çæ áÁá@æ@ ÁÜÖÜÖÁ æç| Á| | | ·æ| Á } æ| ^áÁ ·^·æç| } çæ| } ^Á| | { æá } Á| Áæ * { ^ } çæ| Ááç| | | æÁáá^ Áæç| Á| | Ç@ çæç| } ÈÁV @ | ^| | ^ÁÜÖÜÖÁ çæ| Á·^Á·^áÁ ç| Áá çæ^ Áá ç| ááÁ æ Áæ Á| ç| * |æ·Á á@ çæ| } ^Á çç| } áÁ| Á æ| æ| Èæ áÁá@·Á^ á· çæ| çæ| Á ^· çæ^ } çæ| Á| ç| * |æ·Á| Ááá çæ^ Áá áæç| } Á| Á·^Á Á

Parameters	Novabone—PRIMARY PREDICATE	SHEFABONE (SCPC)
510(k) #	K 040278	pending
Classification & ProCode	Class II, LYC	Class II, LYC
Intended Use	Bone void filler	Bone void filler
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

510(k) Summary-Continued

Parameters	Novabone—PRIMARY PREDICATE	SHEFABONE (SCPC)
	alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. PerioGlas may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either as a bone graft extender.	<ul style="list-style-type: none"> Ridge augmentation (sinusotomy, osteotomy, cystectomy) Extraction sites (ridge maintenance/augmentation, implant preparation/ placement) Sinus lifts Cystic cavities Oral and maxillofacial augmentation
Material Description	ionic Si, Ca, P and Na.	ionic Si, Ca, P and Na.
	Resorbable	Resorbable
Processing	thermal treatment to bond the chemical components together	thermal treatment to bond the chemical components together
Porosity	Dense	Porous
Particle Size	90-710 micron	90-710 micron
Packaging Format	Sealed Plastic cup contains 0.5 CC or Novabone Perioglass particles. Sterilized by Gama radiation	Sealed glass vial contains 1 gm (1cc) of SCPC particles. The vial is sealed in aluminum sterilization pouch. Sterilized by Gama radiation

In addition, Shefabone SCPC is equivalent to aspects of the Reference Predicate K033611: $\text{C}_3\text{H}_7\text{Si}_2\text{O}_8$ is a calcium phosphate based bone graft substitute. It is composed of calcium phosphate particles which are sintered together to form a porous structure. The particles are spherical and have a diameter of 90-710 microns. The material is sterilized by gamma radiation. It is used for alveolar ridge augmentation, dental extraction sites, sinus lifts, and cystic defects. It may be used alone or in combination with autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone).

SUMMARY of TESTING/ BASIS of SUBSTANTIAL EQUIVALENCE:

The testing was conducted to evaluate the safety and effectiveness of Shefabone SCPC compared to Novabone Perioglass. The study included pre-clinical and clinical testing. Pre-clinical testing included histological and radiographic evaluation of bone formation and resorption. Clinical testing included a randomized controlled trial comparing Shefabone SCPC to Novabone Perioglass in the treatment of alveolar ridge defects. The results of the study demonstrated that Shefabone SCPC is substantially equivalent to Novabone Perioglass in terms of safety and effectiveness.

CONCLUSION:

Based on the results of the testing, Shefabone SCPC is substantially equivalent to Novabone Perioglass. The data demonstrate that Shefabone SCPC is safe and effective for the treatment of alveolar ridge defects. Therefore, Shefabone SCPC is approved for use as a bone graft substitute.