K113049

510(K) Summary

JAN 27 2012

SUMMARY REPORT

SUBMITTED BY

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This summary of 510k substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92. Socket Graft is intended to be marketed as a kit containing Socket Graft bone grafting material and a barrier membrane titled Socket Seal.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME for Socket Graft

Classification Name:	Bone grafting material, synthetic
Common/Usual Name:	Bone grafting material
Product Classification:	LYC
Proprietary Name:	SOCKET GRAFT

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME for Socket Seal

Classification Name:	Barrier, Synthetic, Oral
Regulation description:	Bone grafting material
Common/Usual Name:	Barrier, Synthetic, Oral
Product Classification:	NPK
Proprietary Name:	SOCKET SEAL

SOCKET GRAFT grafting material is substantially equivalent to:

1) Socket Graft K052493
2) EquivaBone Osteoinductive Bone Graft K090855
3) CalMatrix Calcium Sulfate Bone Graft K041324

SOCKET SEAL is substantially equivalent to:

1) IMTEC BioBarrier Membrane K974752
2) Tefgen-LS K965205

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DEVICE DESCRIPTION

SOCKET GRAFT is intended to regenerate bone in dental extraction sockets. SOCKET GRAFT is dual phase calcium phosphate biocement that is wetted by sterile water to a putty consistency. Extraction sockets are filled with SOCKET GRAFT and covered by the enclosed Socket Seal. SOCKET GRAFT is fully resorbed in 12-14 weeks resulting in bone filling the extraction socket. SOCKET GRAFT is supplied in sterile, single use 1.5 cc syringes.

Socket Seal is a closed cell, medical grade, polyethylene foam material that is a nonporous, biocompatible semi-rigid sheet. Socket Seal is designed to stabilize, support and protect bone graft material and provide space maintenance for regenerative healing.

INDICATIONS FOR USE

SOCKET GRAFT is a bone grafting material indicated for use in dental extraction sockets that have all walls remaining.

Socket Seal is a temporary implantable material intended for use in the oral cavity to be used as a space maintaining barrier over bone and other tissue. Socket Seal is indicated for use over bone grafts. Socket Seal in indicated for use over extraction sockets in the maxilla and mandible.

PERFORMANCE TESTING:

In comparison to the predicate device Socket Graft K052493comparison summary: Non clinical testing.

	Socket Graft predicate K052493	Socket Graft K113049
Trace impurities analysis Reference US pharmacopeia 34 specification NMT 20 PPM	pass	pass
Particles	none	none
Ca/P ratio	equivalent	equivalent
Ph	7.2	7.4
volumetric porosity	25%	non porous
Solubility @ 20C	non soluble	non soluble

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The proposed device Socket Graft K113049 differs in composition only by the addition of sodium salt of carboxymethylcellulose.

The sodium salt of carboxymethylcellulose used in Socket Graft conforms to the GRAS classification 21 CFR 182.1745 with the following analysis:

reference	test results
99.5% by dry weight	99.8
max substitution 0.95	0.77
minimum viscosity 25 centipoises	3100 centipoises

Predicate devices EquivaBone Osteoinductive Bone Graft and CalMatrix Calcium Sulfate Bone Graft both contain comparable amounts of carboxymethylcellulose and both of these predicate devices have used carboxymethylcellulose to increase the viscosity of their graft material in the same manner as the proposed device Socket Graft K113049 . Carboxymethylcellulose has been shown to resorb in 12 weeks in vivo in the following reference "Carboxymethylcellulose-stabilized collagenous rhOP-1 device—a novel carrier biomaterial for the repair of mandibular continuity defects. Wang H et al".

The predicate device Socket Graft K052493 was shown to fully resorb in 12-14 weeks. The timing of implant placement for Socket Graft K113049 is based on published research for the predicate device Socket Graft K052493. In the published research article "The healing socket and socket regeneration. Compend Contin Educ Dent. 2008 Mar;29(2):114-6, 118, 120-4". One Hundred implants were placed on a protocol of 6 weeks for incisors and bicuspids and 8 weeks for molars. All one hundreds implants integrated and all implants were in function 3 years after placement. Therefore, the earliest time point for implant placement in sockets grafted with Socket Graft K113049 is 8 weeks.

Substantial Equivalence:

Socket graft grafting material and Socket Seal shares indications and design principles with the following predicate devices:

Device name	Proposed Device Socket Graft	Predicate device #1 Socket Graft	Predicate Device #2 EquivaBone Osteoinductive Bone Graft	Predicate Device #3 CalMatrix Calcium Sulfate Bone Graft
510 K number	K113049	K052493	K090855	K041324
Intended use	SOCKET GRAFT is a bone grafting material	SOCKET GRAFT is a bone grafting material	EquivaBone is an osteoinductive bone	used to treat multiple types of maxillary and

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	indicated for use in dental extraction sockets that have all walls remaining.	indicated for use in dental extraction sockets.	graft substitute that is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e.posterolateral spine) and pelvis that are not intrinsic to the stability of the bony structure. These voids or gaps may result from natural occurring bone disease, traumatic injury or surgical intervention.	mandibular osseous and periodontal defects such as: Intrabony/infrabony defects, furcation defects, recession defects, dehiscence/fenestration defects (natural teeth and prosthetic root form implants), extraction socket (ridge preservation) defects, ridge augmentation defects, sinus lift defects, endodontic bony defects
Material	A dual phase calcium phosphate biocement plus carboxymethyl cellulose (CMC) that is wetted by sterile water to a putty consistency.	A dual phase calcium phosphate biocement that is wetted by sterile water to a paste consistency	Synthetic calcium phosphate, carboxymethyl cellulose (CMC) and demineralized bone matrix (DBM) that is wetted by sterile water to a putty consistency.	A calcium sulfate material that contains approximately 10% of pharmaceutical grade sodium carboxymethylcellulose (CMC) that is wetted by sterile water to a putty consistency.
Design	Powder, water	Powder, water	Powder, water	Powder, water
Sterile/ non sterile	Sterile	sterile	Sterile	Sterile
Sterilization method	gamma	gamma	gamma	gamma
Biocompatible	Yes	yes	yes	yes
Resorbable/ Nonresorbable	resorbable	resorbable	resorbable	resorbable

PREDICATE DEVICES for Socket Seal

Device name	Proposed Device Socket Seal	Predicate Device #1 IMTEC BioBarrier Membrane	Predicate Device#2 Tefgen-LS
510 K number	K113049	K974752	K965205
Intended use	A temporary implantable material intended for use in the oral cavity to be used as	A temporary implantable material intended to be used in the oral cavity as a space maintaining barrier	A implant material which is intended to be used in the oral cavity as a temporary space making barrier over

	a space maintaining barrier over bone and connective tissue. Socket Seal is indicated for use over bone grafts. Socket Seal in indicated for use over extraction sockets in the maxilla and mandible.	over bone. Use in augmentation around implants placed in immediate extraction sockets and around implants placed in delayed extraction sockets and should be used in combination with space-making bone graft material.	bone or other tissue.
Material	polyethylene	polyethylene	polyethylene
Design	sheets	Sheets	sheets
Sterile/non sterile	Sterile	Sterile	Sterile
Sterilization method	gamma	Not specified	Not specified
Biocompatible	Yes	yes	yes
Resorbable/ Nonresorbable	nonresorbable	nonresorbable	nonresorbable
porosity	nonporous	nonporous	nonporous

Conclusion (statement of equivalence)

The data submitted in this 510(k) supports substantial equivalence of Socket Graft and Socket Seal to the following aforementioned commercially marketed devices.

Substantial equivalence is based on the indications for use, product design and configuration, and materials used. The intended use of Socket Graft K113049 is the same as Socket Graft K052493, and the materials used are the same as those found in Socket Graft K052493 with the exception of the addition of carboxymethyl cellulose(CMC). Socket The comparative analysis demonstrates the substantial equivalence of Socket Graft and Socket Seal to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN 27 2012

Re: K113049
Trade/Device Name: Socket Graft
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: January 15, 2012
Received: January 23, 2012

Dear Mr. Steiner:

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,

for Anthony D Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

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Indications for Use Statement

510(k) Number (if known) K113049, Socket Graft, January 15 2012

Device Name Socket Graft

Indications for Use SOCKET GRAFT is a bone grafting material indicated for use in dental extraction sockets that have all walls remaining.

Socket Seal is a temporary implantable material intended for use in the oral cavity to be used as a space maintaining barrier over bone and other tissue. Socket Seal is indicated for use over bone grafts. Socket Seal in indicated for use over extraction sockets in the maxilla and mandible."

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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