K111069

SECTION 5
510(K) SUMMARY

SEP 2 2 2011

Submitted on behalf of:
Company Name: Ms. Cynthia Brogan, President
OsteoSymbionics, LLC
1768 East 25th Street
Cleveland, Ohio 44114
Registration No: 3007223102
Phone: (216) 881-8500
e-mail: cb@osteosymbionics.com

Submitted by: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: **715-549-6035**
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CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **September 12, 2011**

Trade or Proprietary Name:	OsteoSymbionics Temporal Implant
Common Name:	Temporal Implant
Classification Name:	Implant, Temporal
Classification	(ProCode): MNF

SUBSTANTIALLY EQUIVALENT TO:
The OsteoSymbionics Temporal Implants (made from silicone elastomer technology) are substantially equivalent to the following legally marketed predicate devices: Implantech, Inc., Implantech Temporal Implant - K943644 (made from silicone elastomer) and Porex Surgical, Inc., Medpor Pterional Surgical Implant - K002568, made from porous polyethylene.

DESCRIPTION of the DEVICE:
The OsteoSymbionics Temporal Implants are pre-formed implantable prosthetic implants intended to fill soft-tissue defects in a patient's cranial/craniofacial temporal region. The implants are composed of long-term implantable-grade solid silicone elastomer. The implants are available in left and right, and come in two different sizes, small and medium. The devices are provided sterile, and are attached to native tissue with commercially available suture materials.

INDICATIONS FOR USE:
The OsteoSymbionics ST Temporalis Implant is Indicated to correct temporal hollowing in patients who have had surgery involving the pterional / Lateral approach to the cranium, including pterional / lateral craniotomy or decompressive craniotomy. The OsteoSymbionics St Temporalis Implant augments the space normally occupied by the temporalis muscle. The Implant is used for the reconstruction of temporal contour deformities; the reconstruction of temporal defects, and / or the augmentation / reconstruction of the space normally occupied by the temporalis muscle / temporal area (s).

SUMMARY of TESTING:
The non-clinical safety and effectiveness data established that the OsteoSymbionics Temporal Implant has comparable chemical characteristics as the Implatech device (based upon literature comparison). Physical property testing included tensile, durometer and tear strength of materials representing the manufacturing and sterilization parameters. Biocompatibility data from the MAF was augmented with an agar overlay cytotoxicity study. Bioburden testing was conducted to support the sterilization testing. LAL testing demonstrated less than 0.005EU/ml. Shelf-life aging labeling claims are supported by product use history.

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

OsteoSymbionics, LLC
% Paladin Medical, Inc.
Elaine Duncan, MS, ME, RAC
P.O. Box 560
Stillwater, Minnesota 55082

SEP 2 2 2011

Re: K111069
Trade/Device Name: OsteoSymbionics ST Temporalis Implant
Regulation Number: 21 CFR 878.3550
Regulation Name: Chin prosthesis
Regulatory Class: II
Product Code: MNF
Dated: September 12, 2011
Received: September 14, 2011

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

Enclosure

K111069

Indications for Use

510(k) Number (if known): _____

Device Name: _____

The OsteoSymbionics ST Temporalis Implant is indicated to correct temporal hollowing in patients who have had surgery involving the pterional / lateral approach to the cranium, including pterional / lateral craniotomy or decompressive craniectomy. The OsteoSymbionics ST Temporalis Implant augments the space normally occupied by the temporalis muscle. The implant is used for the reconstruction of temporal contour deformities; the reconstruction of temporal defects, and / or the augmentation / reconstruction of the space normally occupied by the temporalis muscle / temporal area (s).

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

David Krause for MKM

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

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