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FEB 14 2012

510(k) Summary for K111018

1. Company Making the Submission

	Submitter
Name	AtPac Medical
Address	848 N Rainbow Blvd #3284 Las Vegas, NV 89107
Phone	503.970.4601
Fax	805.669.4221
Contact	Scott Howard
Email	scott@atpacmedical.com

2. Device

Trade Name: OsteoLaso
Common Name: Bone Void Filler
Classification Name: Resorbable Calcium Salt Bone Void Filler

3. Predicate Device: Kasios TCP (K042340)

Biocompatability was tested by using ISO 10993:2003 standards. Results showed equivalence to predicate device of Kasios TCP (K042340). Chemical composition was tested using ASTM International standards section ASTM F1088-87, which is the International Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation. Results showed 99.99% Beta-TriCalcium Phosphate in equivalence to predicate device of Kasios TCP (K042340) at 99.9%Beta-TriCalcium Phosphate. Pore size was tested. Results showed 200-500μm equivalence to predicate device of Kasios TCP (K042340). Percentage of Porosity was tested. Results showed greater than 75% which is equivalent to predicate device of Kasios TCP (K042340) at 60-80%. Finally, OsteoLaso and Kasios TCP are both Indicated for Use as a Bone Void Filler.

4. Description

OsteoLaso Granule & Strips consists of beta-tricalcium phosphate, and polyphosphate. It is the bone graft substitute that regenerates bone after implantation.

5. Indication for Use

OsteoLaso Granule & Strips are intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. OsteoLaso Granule & Strips are indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. OsteoLaso Granule & Strips are intended to be pasked into boney voids or gaps of the skeletal system as a bone void filler (i.e., extremeties, posterolateral spine and pelvis). This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

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6. Review

OsteoLaso Granule & Strips has equivalent technological characteristics to the predicate device in the following ways: Biocompatability, Pore Size, Pore Interconnectedness, Indications for Use. Chemical Properties.

Component Equivalence

OsteoLaso and the predicate are both packed with a container.

Indications for Use Equivalence

OsteoLaso and the predicate are both indicated as a bone void filler.

7. Conclusion

Based on the information provided in this premarket notification AtPac Medical LLC concludes that OsteoLaso Granule & Strips is safe and effective and substantially equivalent to predicate device as described herein.

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

AtPac Medical, LLC
% Mr. Scott Howard
CEO
848 North Rainbow Boulevard, Suite 3284
Las Vegas, Nevada 89107

FEB 14 2012

Re: K111018
Trade/Device Name: OsteoLaso Granule and Strip
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV
Dated: February 6, 2012
Received: February 6, 2012

Dear Mr. Howard:

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,

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

Enclosure

Indication for Use

510(k) Number (if known) __K111018__

Device Name: OsteoLaso Granules & Strips

Indication for Use: OsteoLaso Granules & Strips are intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the boney structure. OsteoLaso Granules & Strips are indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. OsteoLaso Granules & Strips are intended to be packed into boney voids or gaps of the skeletal system as a bone void filler (i.e., extremities posterolateral spine and pelvis). This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Prescription Use __X___AND/OR Over-The-Counter Use _____
(21CRF 801 Subpart D) (21CRF 801 Subpart C)

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

Concurrance of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K111018