

VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Nicolas Guena
Kasios Biomaterials
Z.I. La Croix
8, Impasse de la Feuilleraie
31140 Launaguet
France
Telephone: (33) 5 34 27 33 23
Date Prepared: November 10, 2004.

B. Device Name

Trade or Proprietary Name: *Kasios TCP*
Common or Usual Name: Bone Void Filler
Classification Name: Unclassified

C. Predicate Devices

The subject device is substantially equivalent to similar previously cleared devices.

D. Device Description

The *KASIOS TCP* is a synthetic resorbable calcium phosphate bone void filler. It is an osteoconductive material which provides a porous scaffold upon which bone formation can occur. The interconnected porosity ranges from 60 to 80% with a pore size range of 200 to 500µm. The device is available in a variety of shapes and sizes.

E. Intended Use

Kasios TCP is indicated only for filling bone voids or defects that are not intrinsic to the stability of the bony structure. Kasios TCP is to be gently packed into bony voids or gaps of the skeletal system (such as the extremities, spine and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Kasios TCP is a bone graft substitute that resorbs and is replaced with bone during the healing process.

F. Substantial Equivalence

Data was provided which demonstrated the *KASIOS TCP* to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material, and function.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2004

Mr. Nicolas Guena
Kasios Biomaterials
C/o Excaelia
45900 Parsippany Court
Temecula, California 92592

Re: K042340
Trade/Device Name: Kasios TCP
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: November 10, 2004
Received: November 12, 2004

Dear Mr. Guena:

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.

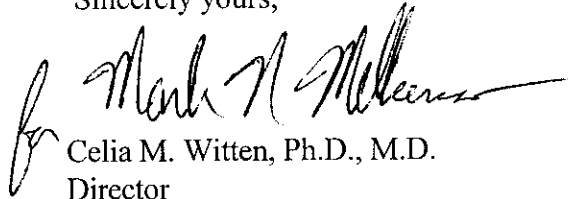
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

A. Indications for Use

510(k) Number (if known): _____

Device Name: Kasios TCP

Indications for Use:

Kasios TCP is indicated only for filling bone voids or defects that are not intrinsic to the stability of the bony structure. Kasios TCP is to be gently packed into bony voids or gaps of the skeletal system (such as the extremities, spine and the pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Kasios TCP is a bone graft substitute that resorbs and is replaced with bone during the healing process.

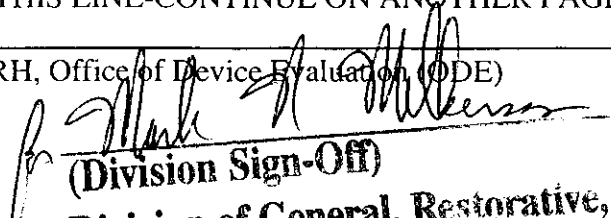
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number _____

K042340