K040134

THERICS, INC.
115 CAMPUS DRIVE
PRINCETON, NJ 08540
TELEPHONE: 609-514-7200
FAX: 609-514-7219
E-MAIL: therics@therics.com

MAR - 9 2004

THERICS'

510(k) SUMMARY

Therics' TheriLink™ Bone Void Filler

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter's Name:

Umberto V. Parrotta
Telephone: 609.514.7237 or 609.514.7200 (main)
Facsimile: 609.514.7219
Contact Person: Umberto V. Parrotta

Date Prepared: January 19, 2004

Name of Device and Name/Address of Sponsor

TRADE/PROPRIETARY NAME OF DEVICE:
TheriLink™ Bone Void Filler

ADDRESS:
115 Campus Drive
Princeton, New Jersey 08540

Common or Usual Name:
Bone Void Filler.
Synthetic Bone Void Filler.
Synthetic Cancellous Bone Void Filler.
Bone Graft Substitute.
Synthetic Bone Substitute.
Synthetic Cancellous Bone Substitute

Classification Name
Bone Void Filler

Predicate Devices
Therics' TheriFil™ Bone Void Filler
Orthovita's Vitoss™

THERICS, INC.
115 CAMPUS DRIVE
PRINCETON, NJ 08540
TELEPHONE: 609-514-7200
FAX: 609-514-7219
E-MAIL: therics@therics.com

THERICS

Intended Use / Indications for Use

TheriLink™ Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e. the extremities, spine and pelvis). TheriLink™ parts create a network within the defect site that resorbs during healing and is replaced by bone.

Technological Characteristics and Substantial Equivalence

The TheriLink™ Bone Void Filler is constructed of synthetic β-tricalcium phosphate (β-TCP), a commonly found mineral in bone. The porosity and geometric features of β-tricalcium phosphate create a network within the defect site that resorbs during healing and is replaced by native bone.

A summary of the physical and chemical characteristics of both TheriLink™ and TheriFil™ is below in Table 1.

Table 1. Physical and chemical characteristics of the TheriLink™ and TheriFil™ .

Characteristic		TheriLink™	TheriFil™
Porosity (%)		58 ± 2.2	59 ± 5.3
Pore Area (μm^2)	Mean	2500 ± 900	3000 ± 1200
	Min*	40	40
	Max	$4.9 \times 10^5 \pm 1.9 \times 10^5$	$3.5 \times 10^5 \pm 2.1 \times 10^5$
Pore diameter (μm)	Mean	55 ± 11	60 ± 12
	Min*	7	7
	Max	770 ± 170	640 ± 220
True Density (grams/mL)		1.5	1.5
Crystallinity		β-TCP > 75%	β-TCP > 75%

Percent porosity and pore area (μm^2) were estimated using SEM images (n = 18) and are described in **Attachment - 13A, Porosity Characterization**. Data are shown as ave ± stdev. The pore diameter was estimated from the pore area by assuming circular shaped pores. *All finite (< 40 μm^2) pore structures were excluded from the analysis and therefore the minimum pore area is represented by 40μm^2 and the pore diameter by 7μm. The true density was measured using a pycnometer.

THERICS, INC.
115 CAMPUS DRIVE
PRINCETON, NJ 08540
TELEPHONE: 609-514-7200
FAX: 609-514-7219
E-MAIL: therics@therics.com

THERICS

The risk assessment comparing the design of TheriLink™ to TheriFil™ indicates minimal additional risk inherent to the design, appearing consistent with similar FDA cleared and marketed products (i.e. Orthovita's Vitoss™).

The TheriLink™ implants have the same intended use and indications, the same or similar principals of operation and technological characteristics, and equivalent performance or characteristics in appropriate bench studies, and risk assessment. Therefore, Theric's Therilink™ Bone Void Filler is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Therics, Inc.
C/o Jonathan S. Kahan
Hogan & Hartson, LLP
555 13th St. NW
Washington, DC 20004

Re: K040134
Trade/Device Name: TheriLink™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: January 21, 2004
Received: February 9, 2004

Dear Mr. Kahan:

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,

for Mark N Milhorn

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

Enclosure

THERICS

TISSUE ENGINEERING SPECIALISTS

CONFIDENTIAL

Attachment – 11

Indications for Use Form

510(k) Number (if known):

Device Name:

TheriLink™ Bone Void Filler

Indications for Use:

TheriLink™ Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (*i.e.*, the extremities, spine and pelvis). TheriLink™ parts create a network within the defect site that resorbs during healing and is replaced by bone.

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

for Mark N Milhous

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

510(k) Number K040134