MAR 2 6 2003

K023998

510(k) Summary

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

THERICS

K023998

510(k) SUMMARY

Therics' TheriRidge™ Block

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: December 2, 2002

Name of Device and Name/Address of Sponsor

TRADE/PROPRIETARY NAME OF DEVICE:
TheriRidge™ Block, Bone Graft Substitute

ADDRESS:
115 Campus Drive
Princeton, New Jersey 08540

Common or Usual Name:
Bone Graft Substitute
Hydroxylapatite (HA) Blocks
Hydroxyapatite (HA) Blocks
Synthetic Bone Substitute

Classification Name
Bone Augmentation Materials

Predicate Devices
Interpore's Pro Osteon® 200

E-MAILED COPY (RSB)

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

TheriRidge™ Block Bone Graft Substitute is indicated and intended for the augmentation of deficient maxillary and mandibular alveolar ridges.

Technological Characteristics and Substantial Equivalence

The TheriRidge™ Block device consists of hydroxylapatite material, the primary mineral content of human bone, with porosity and geometric features that encourage tissue in-growth. The device will be available in three (3) basic sizes: small (approximately 10.4 mm x 5.6 x 5.0), medium (approximately 10.4 mm x 10.0 x 5.0), and large (approximately 20.0 mm x 10.0 x 5.0).

A summary of the physical and chemical characteristics of both TheriRidge™ Block and Pro Osteon® 200 is below in Table 1.

Table 1.

Characteristics	TheriRidge™	ProOsteon 200™
Median Pore Diameter	12 microns	80 microns
Bulk Density	1.7 g/cc	1.3 g/cc
True/Skeletal Density	3.0 g/cc	3.0 g/cc
Porosity	43 % *	57 %
Crystallinity	> 95% HA	> 90% HA
Compressive Strength	4.3 MPa (3 to 6 MPa)	5.8 MPa (4 to 10 MPa)

* Excluding channels

Pre-clinical performance testing conducted on TheriRidge™ and Pro Osteon® 200 in a canine animal model according to indication yielded similar results based on handling characteristics, wound healing, implant stability, and the presence of healthy tissue in or adjacent to the devices.

The TheriRidge™ implants have the same intended use and indications, the same or similar principals of operation and technological characteristics, and equivalent performance in an appropriate animal model. Therefore, Theric's TheriRidge™ Block 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 2 6 2003

Mr. Umberto V. Parrotta, Jr.
Director of QA & RA
Therics, Incorporated
115 Campus Drive
Princeton, New Jersey 08540

Re: K023998
Trade/Device Name: TheriRidge™ Block, Bone Graft Substitute
Regulatory Class: Unclassified
Product Code: LYC
Dated: February 24, 2003
Received: February 25, 2003

Dear Mr. Parrotta:

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) 594-4613. 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

THERICS K023998

CONFIDENTIAL

Attachment – 12

Indications for Use Form

510(k) Number:
K023998.

Device Name:
TheriRidge™ Block, Bone Graft Substitute

Indications for Use:
Theri*Ridge*™ Block Bone Graft Substitute is indicated and intended for the augmentation of deficient maxillary and mandibular alveolar ridges.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Ken Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023998

(Optional Format 1-2-96)