K062452

Special 510(k)
Kit Mendec Spine and delivery system

SEP 21 2006

ATTACHMENT 4

510(k) Summary

510(k) Summary

Official Correspondent: Brauer Device Consultants LLC
1700 Research Boulevard, Suite 220
Rockville, Maryland 20850
Phone: 301-545-1990
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Contact: Christine L. Brauer, Ph.D.

Manufacturer: Tecres S.p.A.
Via Andrea Doria
37066 Sommacampagna
Verona - Italy
FDA Owner/Operator ID #: 9033624

Date: August 22, 2006

Special 510(k)
Kit Mendec Spine and delivery system

510(k) Summary

Trade/Proprietary Name:	Kit Mendec Spine and delivery system
Common Name:	Convenience Kit for percutaneous vertebroplasty
Regulation Number:	888.3027 888.4200
Device Class:	II
Classification Panel:	Orthopedic
Classification Product Code:	NDN, LOD; KIH

Intended Use:
The Kit Mendec Spine and delivery system is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Predicate Device Information
The predicate device is Mendec Spine (K042415).

Device Description
Kit Mendec Spine and delivery system contains an acrylic resin for vertebroplasty and a delivery system. The acrylic resin consists of a powder component and a liquid component. The delivery system consists of a syringe-like device with a "gun-system", an Aspiration tube, an Extension tube and may include, depending on the variant, a Needle.

Substantial Equivalence
The components of the Kit Mendec Spine and delivery system are either exempt from premarket notification or have been found to be substantially equivalent through the premarket notification process for the use for which the kit is to be intended. Any difference that may exist do not significantly affect the substantial equivalence of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2006

Tecres S.p.A
% Christine Brauer, Ph.D.
Brauer Device Consultants
1700 Research Boulevard, Suite 220
Rockville, Maryland 20850

Re: K062452
Trade/Device Name: Kit Mendec Spine and Delivery System
Regulation Number: 21 CFR 888.3027
Regulation Name: Methyl methacrylate for vertebroplasty
Regulatory Class: Class II
Product Code: NDN
Dated: August 22, 2006
Received: August 22, 2006

Dear Dr. Brauer:

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 240-276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Special 510(k)
Kit Mendec Spine and delivery system

ATTACHMENT 2

Indications for Use

510(k) Number (if known):

Device Name: Kit Mendec Spine and delivery system

Indications for Use: The Kit Mendec Spine and delivery system is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use __√__ (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)

K062452 Barbara Ruckup

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

510(k) Number K062452