Exactech

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

MAY 2 8 2004

Tecres Spacer-K

Summary of Safety and Effectiveness
Traditional 510(k)

Applicant/ Consultant:

Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617

Contact: **Gary J. Miller, Ph.D.**
Exec. V.P. of R&D

Manufacturer/Submitter:

Tecres S.p.A
FDA Owner/Operator ID# 9033624

Date: **May 19, 2004**

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Classifications / Proprietary Names:

Classification Name:	Knee joint, femoral and tibial components, polymeric, cemented
Product code:	JWH
C.F.R. Section:	888.3560
Device Class:	II
Classification Panel:	Orthopaedic
Trade / Proprietary Model Names:	Spacer-K Temporary Knee Prosthesis

Legally Marketed Device for Substantial Equivalence Comparison:

The Spacer-K device is substantially equivalent to the "Natural Knee". The device was cleared for marketing through premarket submission #K936159.

Model	Manufacturer	510(k) Number
Natural Knee	Centerplus (Sulzer, Intermedics)	#K936159

Device Description:
The Spacer-K is a temporary device that mimics a "total knee prosthesis". The two-component unconstrained design incorporates a femoral and a tibial component. The device is composed of fully formed gentamicin/polymethylmethacrylate (PMMA) bone cement. The device is supplied sterile to an assurance level (SAL) of 10^{-6}.

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INDICATIONS FOR USE

Spacer-K is indicated for use as a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. Spacer-K is only indicated for an implantation period of 180 days or less. Because of the inherent mechanical limitations of the device material (gentamicin/polymethylmethacrylate), Spacer-K is only indicated for patients who will consistently use traditional mobility assist devices (e.g. crutches, walkers, canes) throughout the implantation period.

CONTRAINDICATIONS

Use of Spacer-K is contraindicated in the following situations:

- The patient's condition is such that a two-stage arthroplasty procedure is contraindicated due to decreased immune response or other relevant systemic clinical conditions.
- Bone loss precluding adequate support of the prosthesis.
- Lack of adequate competence (anatomical and functional) of peripheral ligamentous apparatus and extensor mechanism.
- The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
- Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
- Infection of the TKR cannot be confirmed.
- The infected TKR devices cannot be removed.
- The infecting pathogens are resistant to gentamicin.
- The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
- A systemic or secondary remote infection is suspected or confirmed.
- The patient does not have a TKR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis
- The patient has neuromuscular disorders that do not allow control of the knee joint.
- The patient's weight, age or activity level would cause the surgeon to expect early failure of the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Ms. Lisa Simpson
Senior Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K032522
Trade/Device Name: Spacer-K Temporary Knee Prosthesis
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: March 4, 2004
Received: March 5, 2004

Dear Ms. Simpson:

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) 594-4639. 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 may be obtained 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 Milhern

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

Enclosure

Indications for Use

510(k) Number: #K032522

Device Name: **Spacer-K Temporary Knee Prosthesis**

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- The patient's weight, age or activity level would cause the surgeon to expect early failure of the system.

Prescription Use __X__ or Over the Counter Use __No__

Mark A. Milhous

(Division Sign-Off) Please do not write below this line - use another page if needed.

Division of General, Restorative, and Neurological Devices — rence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K032522