

K112983

DEC 12 2011

510(k) Summary

Official correspondent: Christine L. Brauer, Ph.D.  
US AGENT

Manufacturer/Submitter: Tecres S.p.A.  
Via A. Doria 6  
37066 Sommacampagna  
Verona – Italy  
FDA Owner/Operator ID: 9033624

Date: December 9, 2011

510(k) Number: K112983

Trade/Proprietary model names: Interspace Shoulder

Common name: Temporary Shoulder Prosthesis with Gentamicin

Device classification name: Semi-constrained Cemented Prosthesis Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Cemented or Uncemented

Classification regulation 21 CFR § 888.3690

Regulatory class: Class II

Classification panel: Orthopedic

Classification product code: HSD – Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented  
KWS – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Cemented

Device description: The Interspace Shoulder devices is a temporary device composed of fully formed PMMA bone cement with gentamicin and an inner stainless steel metal core. The design mimics a hemi-shoulder prosthesis.

Indication for Use and Intended Use: Interspace Shoulder is indicated for temporary use (maximum of 180 days) as a shoulder replacement (SR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.  
The head and stem are inserted into the glenoid cavity and the humeral medullary canal, respectively, following removal of the existing implant and radical debridement. The device is

## 510(k) Summary

---

intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Interspace Shoulder is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

The Interspace Shoulder Spacer has the same intended use as the predicate device, the Interspace Shoulder Spacer cleared via K060535. Both devices are intended for use as a temporary shoulder implant for patients undergoing a two-stage revision procedure due to an infection.

### Substantial Equivalence:

The Tecres Interspace Shoulder Spacer device is substantially equivalent to itself. The device has previously been cleared: K060535. The intended use and conditions of use remain the same. This 510(k) application was submitted for the introduction of a metal reinforcing structure into the device and to add a new material supplier.

Performance testing was conducted to verify that implant performance continues to meet the production specifications and be adequate for in vivo application under the temporary conditions of use. Mechanical properties, gentamicin release and stability data were evaluated and found to support the substantial equivalence of the devices.

Based on the same fundamental scientific technology and on the results of the verification activities, it is concluded that the modified Tecres Interspace Shoulder Spacer device is substantially equivalent to legally marketed Tecres spacer device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

DEC 12 2011

Tecres S.p.A.  
% Brauer Device Consultants, LLC  
Christine L. Brauer, Ph.D.  
Regulatory Affairs Consultant  
7 Trailhouse Court  
Rockville, Maryland 20850

Re: K112983  
Trade/Device Name: Tecres Spacer-S  
Regulation Number: 21 CFR 888.3690  
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented  
prosthesis  
Regulatory Class: Class II  
Product Code: HSD, KWS  
Dated: November 18, 2011  
Received: November 18, 2011

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 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.

Page 2 – Christine L. Brauer, Ph.D.

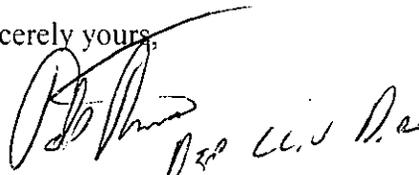
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indications for Use Statement

510(k) Number: K112983

Device Names: Interspace Shoulder

INDICATIONS FOR USE STATEMENT

Interspace Shoulder

Interspace Shoulder is indicated for temporary use (maximum of 180 days) as a shoulder replacement (SR) in skeletally mature patients undergoing a two-stage procedure due to a septic process. The head and stem are inserted into the glenoid cavity and the humeral medullary canal, respectively, following removal of the existing implant and radical debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). Interspace Shoulder is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K112983

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

and/or

Over the Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)