



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 4 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Alexandria Research Technologies, LLC
% Mr. Michael Renner
13755 First Avenue North, Suite 100
Plymouth, Minnesota 55441

Re: K090024

Trade/Device Name: TGS Unicompartmental Knee Arthroplasty

Regulation Number: 21 CFR 888.3520

Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented
prosthesis

Regulatory Class: II

Product Code: HSX, HRY

Dated: April 16, 2009

Received: April 17, 2009

Dear Mr. Renner:

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.

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.

Page 2 - Mr. Michael Renner

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090024

Device Name: TGS® Unicompartmental Knee Arthroplasty System

Indications for Use:

The TGS Unicompartmental Knee Arthroplasty System is intended for arthroplasty of either condyle of a knee with the following indications:

1. Non-inflammatory degenerative joint disease including post-traumatic arthritis and osteoarthritis.
2. Failed previous implant.
3. Correctable deformity.
4. All TGS® UKA System implants are intended for cemented use only.

Components of this system are designed for single use and to be used as a system.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

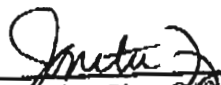
Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

for 

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

510(k) Number K090024



FAX COVER SHEET

Voice Phone Number: 240-276-3788

FDA/Center for Devices and
Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

TO: See addressee on next page
FROM: 510(k) Document Mail Center

Comments: Fax copy of the letter being mailed to you.

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