K090024 #1/2

2 510(k) Summary

Date Prepared: January 2, 2009

MAY - 4 2009

Submitter's Name / Contact Person

Manufacturer
Alexandria Research Technologies, LLC
13755 First Ave. North, Suite 100
Plymouth, Minnesota 55441

Contact Person
Mike Renner
Vice President Operations
Office : 952-949-2235
Fax : 952-949-2007
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General Information

Proprietary Name	TGS® Unicompartmental Knee Arthroplasty System (TGS® UKA System)
Common Name	Compartmental Knee Prosthesis System
Classification Name	CFR 21 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, Class II CFR 21 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis, Class II
Product Device Code	HSX, HRY
Predicate Devices	K010810 DePuy Orthopaedics Preservation Unicondylar Knee Prosthesis K012591 Wright Medical Technology ADVANCE® Unicondylar Knee System

Device Description

The TGS® UKA System is composed of unicompartmental femoral components and unicompartmental tibial components. These components may be used in various combinations to create a single unicompartmental femorotibial replacement for either the medial or lateral side of the knee. TGS® UKA System components include individually packaged femoral components made of cobalt-chromium alloy and all-poly tibial components of ultra-high molecular weight polyethylene with radiographic markers. The femoral components are available in 6 symmetrical sizes for medial or lateral application in right or left knees. The tibial components are available in two sets of 6 sizes; one set for right-medial or left-lateral tibial plateau, and one set for right-lateral or left-medial tibial plateau. Each tibial component size is available in 5 thicknesses with either flat or contoured articular surface, and with either two contoured pegs or anterior-posterior (A/P) keel cement/bone fixation features.

K090024 #2/2

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.

Substantial Equivalence Discussion

The indications for use, principles of operation, materials, sizes, type of interface, fixation, packaging, and sterility of the TGS® UKA System components are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of TGS® UKA System are adequately supported by the substantial equivalence information, materials data, and testing results provided within this premarket notification.

Non-Clinical Testing

Engineering analysis was performed to demonstrate that the TGS® UKA System implant components presented no new risks and are substantially equivalent to the predicate devices.

Clinical Testing

Clinical testing was not necessary to demonstrate substantial equivalence between the subject TGS® UKA System implant components and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2009

Alexandria 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.

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" (21CFR 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,

Barbara Bucher MD for

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:

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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)

(Posted November 13, 2003)

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

510(k) Number K090024