K101206 #1/3

2 510(k) Summary

Date Prepared: April 27, 2010

JUL 23 2010

Submitter's Name / Contact Person

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

Contact Person
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General Information

Proprietary Name	TGS® Unicompartmental Knee Arthroplasty Modular Tibia 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	DePuy Preservation ™ Unicondylar Tibia (K040268, Cleared: May 5, 2004) Genesis Unicompartmental Knee System (Accuris), Smith & Nephew (K912735, Cleared: December 27, 1991) TGS® Unicompartmental Knee Arthroplasty System (K090024, Cleared: May 4, 2009)

Device Description

TGS® Unicompartmental Knee Arthroplasty Modular Tibia System (Modular Tibia) is designed to be used with the TGS® Unicompartmental Knee Arthroplasty System (K090024). The Modular Tibia is designed as a two piece construction including a tibial baseplate and a (poly) tibial insert. The tibial baseplate is composed of titanium alloy and is provided in six sizes. The tibial baseplate is indicated for cemented use only. The tibial insert is composed of ultra-high molecular weight polyethylene and is provided in six sizes corresponding to each metal baseplate size. Each tibial insert size is provided in four thicknesses. The tibial insert assembles to a corresponding tibial baseplate with a snap-fit lock mechanism. The Modular Tibia is provided in right and left configurations for use in the medial or lateral tibiofemoral compartment of the knee. The Modular Tibia is packaged sterile with each tibial baseplate and each tibial insert packaged individually.

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Comparison of Subject to Predicate

	Subject Device	*Predicate #1*	*Predicate #2*	*Predicate #3*
	TGS® UKA Modular Tibia System	**DePuy Preservation (K040268)**	**Smith & Nephew Genesis (Accuris) (K912735)**	**TGS® UKA System (K090024)**
Tibial Insert				
Material	UHMWPE	UHMWPE	UHMWPE	UHMWPE
Interface	Anterior/Posterior snap fit	Anterior/Posterior snap fit	Medial/Lateral snap fit	N/A
Thickness (Combined)	8, 9, 10 & 11 mm	9.5, 11.5 & 13.5mm	8, 9, 10,11 &12mm	7, 8, 9, 10 & 11mm
Sizes	40, 44, 48, 52, 56, 60mm A/P	41, 45, 49, 53, 57mm A/P	38.0, 41.7, 45.6, 48.8, 52.3, 55.4mm A/P	40, 44, 48, 52, 56, 60mm A/P
Sterilization	Ethylene Oxide Sterilization	Gamma Sterilization	N/A	Ethylene Oxide Sterilization
Packaging	Sterile devices are packaged in Double Barrier Thermoform Trays (PETG) with Tyvek Lids	Sterile devices are packaged in GVF Foil Packaging with outer Poly Pouch.	N/A	Sterile devices are packaged in Double Barrier Thermoform Trays with Tyvek Lids
Tibial Baseplate				
Material	Titanium	CoCr	Titanium	
Fixation	1) Double contoured pegs, 2) Single A/P keel. Contact surface has cement pockets. Cement fixation.	Keel with cement pocket	Post , Keel and Cement Pocket	
Baseplate Thickness	2mm	2mm	2mm	
Sizes	40, 44, 48, 52, 56, 60mm A/P	41, 45, 49, 53, 57mm A/P	38.0, 41.7, 45.6, 48.8, 52.3, 55.4mm A/P	
Sterilization	Ethylene Oxide	Gamma Sterilization	N/A	
Packaging	Sterile devices are packaged in Double Barrier Thermoform Trays with Tyvek Lids	Sterile devices are packaged in Double Barrier Thermoform Trays with Tyvek Lids	N/A	

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

K101208 #3/3

Substantial Equivalence Discussion

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

Non-Clinical Testing

The following bench testing and analysis has been performed to demonstrate that the TGS UKA Modular Tibia presented no new risks and is substantially equivalent to the predicate devices:

- Bench testing of the modular component interlock of subject and predicate devices.
- Engineering analysis of strength and fatigue properties of subject and predicate devices.
- Engineering analysis of range of motion and contact area/stress of subject and predicate devices

Clinical Testing

Clinical testing was not necessary to demonstrate substantial equivalence of the subject device, the Modular Tibia, to the indicated predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Alexandria Research Technologies, LLC
% Michael Larson
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JUL 23 2010

Re: K101206
Trade/Device Name: TGS® UKA Modular Tibia System
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 28, 2010
Received: May 03, 2010

Dear Mr. Larson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

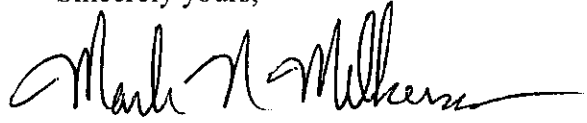
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K101206

Device Name: TGS® UKA Modular Tibia System

INDICATIONS

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.
5. 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)

(Posted November 13, 2003)

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

510(k) Number K101206