K100370 # 1/4

SIGNAL MEDICAL CORPORATION

ORTHOPAEDICS

MAR - 7 2011

Section 5:

510(k) Summary

21 CFR 807.92

1. Submitted by:

Submitter's Name	Signal Medical Corporation
Address:	1000 Des Peres Road, Suite 140 St. Louis, MO 63131 P: 314-775-0518 F: 314-775-0524
Establishment Registration#:	1932213
Correspondent:	Brian Katerberg; Leo Whiteside, MD; Louis Serafin, MD
Date:	March 4, 2011

2. Device Name:

Trade Name:	Symmetric™ Total Knee Augments
Proprietary Name:	Signal Medical Corp. Symmetric™ Total Knee Augments
Common Name:	Knee Prosthesis
Classification Name:	- Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, metal/polymer (888.3560 - JWH)

3. Device Class

Regulatory Class:	Class II
Product Code:	JWH
Panel:	Orthopedic
Regulation Number:	21 CFR 888.3560

4. Predicate Device:

Symmetric™ Total Knee System (K080199), Revision Knee System (K043440), Regenerex Ultra Porous Construct - Titanium Knee Augments (K053505), Regenerex Porous Titanium Sleeve Augments (K072336), Trabecular Metal Tibial Cone Augments and Trabecular Metal Femoral Cone Augments (K053340), Genesis II Total Knee System (K953274)
Similarities to these components are based on design, indications for use, and materials.

	Category	Symmetric Total Knee Augments	Symmetric Total Knee System	Smith & Nephew Revision Knee System	Regenerex™ Ultra Porous Construct - Titanium Knee Augments	Regenerex™ Porous Titanium Sleeve Augments	Trabecular Metal™ Tibial and Femoral Cone Augments	Genesis II Total Knee System
	510K #	K100370	K080199	K043440	K053505	K072336	K053340	K953274
	Intended Use	Cemented	Cemented	Cemented	Cemented/less	Cemented/less	Cemented/less	Cemented
Femoral Wedges	Thickness	5-10mm posterior, 5-15mm distal	NA	Similar	Similar	NA	NA	NA
	Fixation Method	Cemented to implant	NA	Cemented to implant	Cemented or screwed to implant	NA	NA	NA
	Material	Titanium 6Al-4V	NA	Titanium 6Al-4V	Titanium 6Al-4V	NA	NA	NA
	Coating	Titanium Plasma Spray ASTM F1580	NA	NA	Regenerex™ Titanium Porous Coating ASTM F1580	NA	NA	NA
Tibial Wedges	Thickness	5-10mm posterior, 5-15mm distal	NA	Similar	Similar	NA	NA	NA
	Fixation Method	Cemented to implant	NA	Cemented to implant	Cemented or screwed to implant	NA	NA	NA
	Material	Titanium 6Al-4V	NA	Titanium 6Al-4V	Titanium 6Al-4V	NA	NA	NA
	Coating	Titanium Plasma Spray ASTM F1580	NA	NA	Regenerex™ Titanium Porous Coating ASTM F1580	NA	NA	NA
Femoral Cone	ML Width	47-77mm	NA	NA	NA	Similar	Similar	NA
	Height	28-46mm	NA	NA	NA	Similar	Similar	NA
	Fixation Method	Cemented onto femoral component	NA	NA	NA	Cemented onto femoral component	Cemented onto femoral component	NA
	Material	Titanium 6Al-4V	NA	NA	NA	Regenerex™ - Titanium	Tantalum Trabecular Metal™	NA
	Coating	Titanium Plasma Spray ASTM F1580	NA	NA	NA	Regenerex™ - Titanium Plasma Spray ASTM F1580	Tantalum Trabecular Metal™	NA
Tibial Cone	ML Width	45-70mm	NA	NA	NA	Similar	Similar	NA
	Height	18-30mm	NA	NA	NA	Similar	Similar	NA
	Fixation Method	Cemented onto tibial component	NA	NA	NA	Cemented onto tibial component	Cemented onto tibial component	NA
	Material	Titanium 6Al-4V	NA	NA	NA	Regenerex™ - Titanium	Tantalum Trabecular Metal™	NA
	Coating	Titanium Plasma Spray ASTM F1580	NA	NA	NA	Regenerex™ - Titanium Plasma Spray ASTM F1580	Tantalum Trabecular Metal™	NA
Offset Trunnion	Offset Distance	4mm	NA	NA	NA	NA	NA	Similar
	Extension Length	50mm	NA	NA	NA	NA	NA	Similar
	Fixation Method	Morse Taper	NA	NA	NA	NA	NA	Morse Taper
	Material	Titanium 6Al-4V	NA	NA	NA	NA	NA	Titanium 6Al-4V
Stems	Length	100, 150, 200mm	100, 150, 200mm	Similar	NA	NA	NA	Similar
	Diameter	10 through 26mm	10 through 26mm	Similar	NA	NA	NA	Similar
	Fixation Method	Morse Taper	Morse Taper	Morse Taper	NA	NA	NA	Morse Taper
	Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V	NA	NA	NA	Titanium 6Al-4V
	Coating	Titanium Plasma Spray ASTM F1580	NA	none	NA	NA	NA	none

K100370 # 2/4

K100370 #3/4

5. Device Description:
The Symmetric™ Total Knee Augments are intended to complement the Symmetric Total Knee System. The system consists of metallic wedges, stems, cones, sleeves, and offset trunnions that can be used with the Symmetric Total Knee System to provide increased bone contact and support during total knee arthroplasty when more conservative methods have failed.

The FEMORAL WEDGES are designed to fill voids remaining in the peripheral bone stock after the removal of diseased and damaged bone, and to provide indirect bone support for the femoral component. These wedges are made of Titanium 6Al-4V and have grit blasted surfaces where they are designed to be cemented to Symmetric Total Knee femoral implants and titanium plasma sprayed surfaces to provide good cemented fixation to bone. The components are available for the distal and posterior surfaces individually or combined. These wedges are symmetric so they will work on the medial or lateral side of either knee.

The TIBIAL WEDGES are designed to fill voids remaining in the peripheral bone stock after the removal of diseased and damaged bone, and to provide indirect bone support for the tibial component. These wedges are made of Titanium 6Al-4V and are designed for cemented fixation to Symmetric Total Knee tibial implants. The titanium plasma sprayed surfaces provide increased fixation for bone cement. The components are available in flat and wedged designs, and are able to be used on the medial or lateral side of the symmetric trays.

The TIBIAL and FEMORAL Cones are designed to fill voids remaining in the central bone stock after the removal of diseased and damaged bone, and to provide indirect bone support for the femoral or tibial component. These cones are symmetrically designed components designed for cemented fixation around the trunnion or revision stem of a Symmetric total knee implant. The cones are made of Titanium 6Al-4V and are internally grit blasted for cement fixation against the implant and externally plasma sprayed to provide increased cemented fixation to bone.

The OFFSET TRUNNIONS are designed to be attached to the trunnion of the femoral or tibial component utilizing a Morse Taper, and then has a Morse Taper of its own to receive a revision stem. The offset stems are made of Titanium 6Al-4V, and are designed to provide adjustments in stem position with respect to the primary implants trunnion, allowing the stem to line up with the patient's medullary canal more effectively.

The COATED AND PARTIALLY COATED REVISION STEMS are designed to be attached to the trunnion of the femoral or tibial component utilizing the Morse Taper. The stems are made of Titanium 6Al-4V and are titanium plasma sprayed to provide increased fixation.

The RECTANGULAR REVISION STEMS are designed to be attached to the trunnion of the femoral or tibial component utilizing the Morse Taper. The stems are made of Titanium 6Al-4V and are available in non-coated and titanium plasma spray coated styles. The rectangular shape is designed to provide cortical bone support while reducing cancellous bone loss.

K100370 #4/4

6. Device Intended Use:
The Symmetric™ Total Knee Augments consist of single use components intended for attachment to the Symmetric Total Knee implants during total knee arthroplasty with the following indications.

1. Osteoarthritis
2. Rheumatoid Arthritis
3. Traumatic Arthritis or correction of posttraumatic joint deformity
4. Where the use of a more conservative procedure has failed or is unacceptable.

All components are for cemented use.

Additional indications for use:

- Whenever a cone is used, a revision stem is to be used as well.

Material Characteristics:

COMPONENT	CLEARED DEVICE	NEW DEVICE
Femoral Wedges	ASTM F1472	ASTM F1472
Tibial Wedges	ASTM F1472	ASTM F1472
Femoral and Tibial Cones	ASTM F1472	ASTM F1472
Offset Trunnion	ASTM F1472	ASTM F1472
(Partially) Coated Stems	ASTM F1472	ASTM F1472
Rectangular Revision Stems	ASTM F1472	ASTM F1472
Plasma Spray Coating	ASTM F1580	ASTM F1580

7. Performance Summary:

Non-Clinical Testing:
A writeup of the testing completed for this 510(k) is included in Section 18. Testing included compressive fatigue and static testing, torsional testing, and assembly/disassembly testing of the offset trunnion with a tray and stem.

Clinical Testing:
No clinical data was utilized for the basis of substantial equivalence.

Conclusions:
Based on the Symmetric Total Knee System having the same intended use, the results of the non-clinical tests being substantially equivalent to or better than those of at least one predicate device, and the indications for use being similar, we feel that there are no new questions of safety or effectiveness.

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

Signal Medical Corporation
% Mr. Brian Katerberg
Engineer
1000 Des Peres Road, Suite 140
Saint Louis, Missouri 63131

MAR - 7 2011

Re: K100370
Trade/Device Name:
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 25, 2011
Received: March 2, 2011

Dear Mr. Katerberg:

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,

for

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

Enclosure

Section 4:

Indications for Use

510K Number: K100370

Device Name: Symmetric™ Total Knee Augments

Indications For Use:

The Symmetric™ Total Knee Augments consist of single use components intended for attachment to the Symmetric Total Knee implants during total knee arthroplasty with the following indications.

1. Osteoarthritis
2. Rheumatoid Arthritis
3. Traumatic Arthritis or correction of posttraumatic joint deformity
4. Where the use of a more conservative procedure has failed or is unacceptable.

All components are for cemented use.

Additional indications for use:

- Whenever a cone is used, a revision stem is to be used as well.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100370