November 9, 2017

OTIS Biotech Co., Ltd.
Sanjay Lingot
Research Scientist
15-118. Mtv Buk-ro, 193beon-gil
Building 14, 2nd Floor, Siheung-
Siheung-si, 15118 Korea

Re: K170534
Trade/Device Name: Prolixus™ Total Knee System
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: October 10, 2017
Received: October 10, 2017

Dear Mr. Lingot:

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.

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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

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

Enclosure

006. Indications for Use

510(k) Number:

Device Name: PROLIXUS™ TOTAL KNEE SYSTEM

Indications for Use:

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis**,** primary and secondary traumatic arthritis, polyarthritis,collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cement use only.

Prescription Use __Yes__	AND/OR	Over-The-Counter Use __No__
(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)

007. 510 (k) Summary

[As Required by 21 CFR 807.87(h) & 21 CFR 807.92]

1. Submission information

Name of Company: OTIS Biotech Co., Ltd
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Prepared Date: 15-02-2017
Updated Date : 08-11-2017

2. Device Identification

Trade Name: PROLIXUS™ TOTAL KNEE SYSTEM
Common Name: Cruciate Retaining Total Knee Replacement

Classification: **Class Ⅱ (Special Control)**

- 21 CFR 888.3560 – Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained

Product Code : **JWH**.

3. Substantial Equivalence Predicate Legally Marketed Devices

The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the below listed predicate devices.

Manufacturer	Device Name	Submission Number	Clearance date
Osteonics Corp	Omnifit® Total Knee System	K863668	12/19/1986
Stryker Orthopaedics (Howmedica Osteonics Corp)	Duracon® Total Knee System	K032163	09/12/2003
	Triathlon™ Cruciate Retaining	K040267	05/05/2004

	(CR) Total Knee System		
Zimmer, Inc	NexGen CR knee	K933785	30/01/1995
	NexGen (CR) - Flex Femoral components	K023211	17/10/2002
Otis Biotech	MultiFitM Total Hip System (Instruments & Sterilization)	K101472	05/01/2011
	ULC spinal pedicle screw system (Instruments only)	K083077	26/10/2009

4. Device Description

The Prolixus™ Cruciate Retaining (CR) Total Knee System consists of three primary components: Cruciate Retaining (CR) Femoral Component, Cruciate Retaining (CR) Tibial Insert, Patellar component and Tibial base plate.

The Prolixus™ CR components are described below:

PROLIXUS™Total Knee Cruciate Retaining (CR) Femoral Component

Prolixus™ Total Knee Cruciate Retaining (CR) Femoral Component is fabricated from cast cobalt-chromium-molybdenum alloy, and is intended for cemented application to replace the articulating surface of the distal femur. This cruciate retaining femoral component is utilized when total knee replacement is indicated, and accommodates the posterior cruciate ligament if it is present.

The Cruciate Retaining (CR) Femoral Component is available in right and left configurations, and six proportional sizes (sizes A to F) to accommodate differences in patient anatomy. The interior surface of the component is grit-blasted to increase surface roughness - this is intended to promote interdigitation of the polymethylmethacrylate (PMMA) bone cement with the surface texture and the apposing bone. This femoral component features cast-in pegs to help in femoral component placement, and to provide rotational stability.

PROLIXUS™ Cruciate Retaining (CR) Tibial Insert

The Cruciate Retaining (CR) Tibial Insert is neutral in configuration, and is available in six proportional sizes (sizes 1 to 6) and varying thicknesses (10mm, 12mm,14mm, 16mm, 18mm and 20 mm). The insert is fabricated from ultra high molecular weight polyethylene(medical grade PUR 1020 UHMPE) .The tibial insert is designed to accommodate the posterior cruciate ligament if it is present. There is a relief on the

anterior aspect of the tibial insert to accommodate the patellar tendon and patellar fat pad.

PROLIXUS™ Tibial base plate

The angled Stem tibial baseplate components (tibial baseplate) are made from Ti-6Al-4V titanium alloy. Tibial baseplates are available in 6 sizes (1 to 6).

PROLIXUS™ Patellar components

The patellar component is made from ultra high molecular weight polyethylene(medical grade PUR 1020 UHMPE). The patella is available in five diameters, 26mm, 29mm, 32mm, 35mm and 38mm, which permit optimal bone coverage and surgical options.

5. Indications for Use

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyar-thritis,collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cemented use only.

6. List of the Bench tests conducted

A. Test by EndoLab Mechanical Engineering GmbH

1.Fatigue test (Tibial base plate)
2.Knee constraint test
3.Knee Tibia and inserter component interlock strength test
4.Knee Femoral and Tibial insert contact area/pressure distribution test
5.Knee Femoral and Patella contact area/pressure distribution
6.Knee geometry and surfaces
7.Range of motion CAD analysis

B. Greenpia Technology, South Korea

1. Bacterial endotoxins test (BET), also known as the Lims Amebocyte Lysate (LAL) test)

C. Summary & Conclusions fromTestings

1. Fatigue test (Tibial base plate)
   Five tibial trays tested herein at a maximum load of 900 N (200 lbs) passed 10 million load cycles without failure and therefore meet the suggested minimum

fatigue strength by the ISO 21536.This results in a max. run- out bending moment of 22.5 Nm.

2. **Knee constraint test**

Anterior-posterior constraint test

The knee implant tested by the constraint test was found to withstand at 0° flexion a mean anterior load of -348 N (StdDev 9) and a mean posterior load of 149 N (StdDev4).

The knee implant tested by the constraint test was found to withstand at 15° flexion a mean anterior load of -348 N (StdDev12) and a mean posterior load of 147 N (StdDev2).

The knee implant tested by the constraint test was found to withstand at 90° flexion a mean anterior load of -349 N (StdDev3) and a mean posterior load of 154 N (StdDev4).

The knee implant tested by the constraint test was found to withstand at 135° flexion a mean anterior load of -331 N (StdDev5) and a mean posterior load of 152 N (StdDev4).

Medial lateral constraint test

The knee implant tested by the constraint test was found to withstand at 0° flexion a mean lateral load of -396 N (StdDev3) and a mean medial load of 387 N (StdDev6).

The knee implant tested by the constraint test was found to withstand at 15° flexion a mean lateral load of -385 N (StdDev7) and a mean medial load of 383 N (StdDev3).

The knee implant tested by the constraint test was found to withstand at 90° flexion a mean lateral load of -415 N (StdDev3) and a mean medial load of 365 N (StdDev3).

The knee implant tested by the constraint test was found to withstand at 135° flexion a mean lateral load of -370 N (StdDev21) and a mean medial load of 413 N (StdDev5).

Internal-external rotation constraint test

The knee implant tested by the constraint test was found to withstand at 0° flexion a mean external torque of -5.7 Nm (StdDev 0.4) and a mean internal torque of 5.8 Nm (StdDev 0.2).

The knee implant tested by the constraint test was found to withstand at 15° flexion a mean external torque of -6.2 Nm (StdDev 0.3) and a mean internal torque of 5.8 Nm (StdDev 0.1).

The knee implant tested by the constraint test was found to withstand at 90° flexion a mean external torque of -5.4 Nm (StdDev 0.1) and a mean internal torque of 6.3 Nm (StdDev 0.1).

The knee implant tested by the constraint test was found to withstand at 135° flexion a mean external torque of -5.1 Nm (StdDev 0.4) and a mean internal torque of 5.7Nm (StdDev 0.1).

3. Knee Tibia and inserter component interlock strength test

i. Disassembly Test by Anterior/Posterior Loading

a. A total of six specimens were tested for tibial insert and tibial baseplate assembly in anteriorposterior loading direction. In this loading direction the established mean assembly load was found to be 138 N (StdDev 22). An additional orthogonal load was found required for complete assembly.

b. A total of six specimens were tested for tibial insert and tibial baseplate disassembly in posterioranterior loading direction. In this loading direction the established mean disassembly load was found to be **1,459 N** (StdDev 31). Plastic deformation of the snap-in locking mechanism was found as failure mode.

ii. Disassembly Test by Medial/Lateral Loading

One tibial insert and tibial baseplate assembly loaded in medial-lateral load direction was found to withstand loads > 754 N. At this load the point of load application was plastically deformed and test was stopped. No failure at the interconnection mechanism between the tibial insert and the tibial baseplate was found.

One tibial insert and tibial baseplate assembly loaded in lateral-medial load direction was found to withstand loads > 720 N. At this load the point of load application was plastically deformed and test was stopped. No failure at the interconnection mechanism between the tibial insert and the tibial baseplate was found.

iii. Disassembly Test by Pull-off Loading

Tibial insert and tibial baseplate assemblies loaded in tensile mode was found to withstand a mean ultimate load of **2,015 N** (StdDev 187) without the ability of tibia tilt.

iv. Assembly Test in anteriorposterior direction

A total of five specimens were tested for tibial insert and tibial baseplate assembly in anteroposterior loading direction with a tibial baseplate inclination of 70°(30° in top). In this loading direction a mean assembly load of 132 N (StdDev. 24) was determined at a displacement of 4.5 mm.

v. Disassembly Test in anteriorposterior direction and lateral direction

A total of five specimens were tested for tibial insert and tibial baseplate disassembly in anterior to posterior loading direction. In this loading direction a mean ultimate disassembly load of 804 N (StdDev. 70) was determined.

4. Knee Femoral and Tibial insert contact area/pressure distribution test

The area of the contact stresses above 20 MPa found corresponds to typical findings. A direct comparison to the EndoLab database (n=19 test series) can be found.Please note that the data comprises different designs and implant sizes. It can be stated that the contact stresses and total contact areas of implant tested herein are within the common range of the predicate devices.

5. Knee Femoral and patella contact area/pressure distribution

The aim of the test performed was to evaluate the pressure distribution and total contact area of the patella-femoral components under different flexion angles and loads.The smallest total contact area of the patella-femoral joint was 20.44 mm^2 (SD 0.29 mm_2) at 15° flexion and the largest total contact area was 86.87 mm^2 (SD 0.92 mm_2) at 135° flexion.The smallest contact area above 20 MPa was 11.61 mm_2 (SD 0.50 mm_2) at 15° flexion and the highest contact area above 20 MPa was 66.07 mm_2 (SD 1.35 mm_2) at 135° flexion.

6. Knee geometry and surfaces

Femoral component-

In accordance to ISO 7207-2 the articulating surface roughness has been described by the parameters Ra, Rz and Rt for five femoral components.

Related to the demands of ISO 7207-1 the geometric dimensions were determined for the same five femoral components

Surface finish:

A total mean Ra value of 0.013 µm (Std. Dev. 0.001 µm) was measured.

A total mean Rz value of 0.194 µm (Std.Dev. 0.279 µm) was measured.

A total mean Rt value of 0.127 µm (Std.Dev. 0.003 µm) was measured.

Referenced to the surface finish requirements according to ISO 7207-2 no femoral component exceeded a roughness value Ra grated than 0.1 µm.

Tibia base component-

The purpose of this analysis was to determine the geometric dimensions of five tibial trays according to ISO 7207-1 and to determine the surface roughness at the femoral surface of the tibial trays.

Surface finish:

A total mean Ra value of 0.62 µm (Std. Dev. 0.078 µm) was measured.

A total mean Rz value of 3.37 µm (Std.Dev. 0.410 µm) was measured.

A total mean Rt value of 5.05 µm (Std.Dev. 0.954 µm) was measured.

Tibia insert component-

The purpose of this analysis was to determine the minimum thickness of five unconstrained bi compartmental (fixed bearing) tibial inserts and to determine the surface roughness at the load bearing side of the tibial inserts.

Surface finish:

An overall mean Ra value of 0.212 µm (Std. Dev. 0.079 µm) was measured.

An overall mean Rz value of 1.084 µm (Std. Dev. 0.391 µm) was measured.

An overall mean Rt value of 1.776 µm (Std. Dev. 0.598 µm) was measured.

Referenced to the surface finish requirements according to ISO 7207-2 , no insert exceeded a roughness value Ra greater than 2.0 µm. The surface roughness values determined for each insert at the different locations are shown

.

Minimum thickness:

A total mean lateral thickness of 6.77 mm (Std. Dev. 0.05 mm) and a total mean medial thickness of 6.77 (Std. Dev. 0.05 mm) have been determined.

ISO 21536: 2007 (Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants) requires a minimum thickness in the load bearing area of 6 mm for components having a tibial tray. None of the inserts analyzed showed a minimum thickness smaller than 6 mm .

Patella component-

In accordance to ISO 7207-2 the interested articulating surface roughness has been determined by the parameters Ra, Rz and Rt for six patella components.

Related to the demands of ISO 7207-1 the minimum thicknesses of have been determined for the same six patella components listed above.

Surface finish:

An overall mean Ra value of 0.79 µm (Std. Dev. 0.20 µm), an overall mean Rz value of 3.20 µm (Std.Dev. 0.65 µm) and an overall mean Rt value of 4.18 µm (Std. Dev. 0.98 µm) were determined.Referenced to the surface finish requirements according to ISO 7207-2 (see section 5.1) no patella component exceeded a roughness value Ra greater than 2.0 µm. The surface roughness values determined for each patella component at the different locations are shown .

Minimum thickness and width dimensions:

An overall mean thickness of 8.01 mm (Std. Dev. 0.05 mm) and an overall mean width of 25.98 (Std.Dev. 0.02 mm) have been determined.

7. Range of motion CAD analysis

A CAD analysis of the TKR Otis Size 1 system has been performed using IGES files .A total of four different rotations/translations have been investigated: Flexion/extension, rotation,medial-lateral and anterior posterior translation. In addition, the medial as well as the lateral contact point have been investigated for seven different flexion angles. All motions observed correspond to typical findings as expected for fixed type bearings. The sliding/rolling analysis supports the common theory of mixed sliding/rolling articulations for this type of bearing. Varus/valgus rotation and proximal/distal translation are not constrained by this type of implant and have not been simulated. Due to the low degree of constraint, different types of articulating motions are expected in-vivo depending on the soft tissue balance, the muscular status as well as the daily living activities of the patient. The analysis of the kinematics presented herein therefore should be regarded as average positioning within an array of possible motions.

8. Pyrogen and Endotoxins Testing : Bacterial endotoxins test (BET), also known as the Limulus amebocyte lysate (LAL) test) :

As a result of endotoxin test validation for thThe PROLIXUS™ Cruciate Retaini ng (CR) Total Knee System, it was confirmed that the endotoxin test reagent (PTS

cartridge) and the laboratory environment were suitable for endotoxin test by the initial qualification test. Inhibition/enhancement Tests conclude that the product is suitable for endotoxin testing using both PTS readers and PTS cartridge, meeting both endotoxin standards and established criteria for testing.

7. Summary of the technological similarities of the new device in comparison to those of the predicate device

Parameter	OTIS Biotech. PROLIXUS™ Knee system	Osteonics Corp Omnifit® Total Knee System	Stryker Orthopaedics (Howmedica Osteonics Corp) Triathlon™ (CR) Total Knee System Duracon® Total Knee System	Zimmer, Inc NexGen CR and (CR)-Flex knee	Remark
Product Code	JWH	JWH	JWH ,MBH	JWH	Similar with predicate device
Indication for Use	1.knee arthroplasty for reduction or relief of pain 2. Improved knee function in skeletally mature patients 3. knee pain and disability due to rheumatoid arthritis 3.Osteoarthritis, primary and secondary traumatic arthritis 4.Polyar-thritis,collagen disorders, avascular	Similar	1.Painful, disabling joint disease of the knee resulting from: non inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis 2. Post-traumatic loss of knee joint configuration and function 3. Moderate varus, valgus or	1.knee arthroplasty for reduction or relief of pain 2. Improved knee function in skeletally mature patients 3. knee pain and disability due to rheumatoid arthritis 3.Osteoarthritis, primary and secondary traumatic arthritis 4.Polyar-thritis,collagen	Similar with predicate device

	necrosis of the femoral condyle **5.Pseudogout, osttraumatic loss of joint configuration** **6. Patellofemoral erosion, dysfunction** **7. Moderate valgus, varus, or flexion defonnities** **8. Device system is designed for cemented use only.**		**flexion deformity in which the ligamentous structures can be returned to adequate function and stability** **4. Revision of previous unsuccessful knee replacement or other procedure** **5. Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques** ➢ **Duracon knee products are intended to achieve fixation with and without bone cement**	**disorders, avascular necrosis of the femoral condyle** **5.Pseudogout, osttraumatic loss of joint configuration** **6. Patellofemoral erosion, dysfunction** **7. Moderate valgus, varus, or flexion defonnities** **8. Device system is designed for cemented use only.**	

Intended for Cement use only	**Yes**	**yes**	➢ **Duracon knee products are intended to achieve fixation with and without bone cement**	**yes**	**Similar with predicate device**
Design and components	**Knee design contains** ➢ **Femoral component** ➢ **Tibial component** ➢ **UHMWPE inserter** ➢ **patella component** **Femoral component- 6 sizes of Left and right side components** **-AP-52,56,60,64,68,72 mm and ML-56,60,64,68,72,76 mm** **Tibial component- 6sizes of tibial component** **-AP-42,44.5,47,50.5,50.5,55.5 mm and ML-63,67,71,71,80,80 mm** **UHMWPE insert- 6 sizes of inserter components**	**Design is almost similar except in component sizes and liner inter locking system between Tibia base plate and UHMWPE**	**The Triathlon CR Total Knee System consists of femoral component tibial insert, and all polyethylene patellar components that are intended to be used with previously cleared Triathlon Primary Cemented Tibial Tray in primary or revision total knee arthroplasty. The Triathlon All Polyethylene Patellar components are intended to be used with femoral components of the previously released Triatihlon PS femoral components of the**	**Knee design contains** ➢ **Femoral component** ➢ **Tibial component** ➢ **UHMWPE inserter** ➢ **patella component** **Design is almost similar except in component sizes and liner inter locking system between Tibia base plate and UHMWPE**	**Design is almost similar except in component sizes and Tibia base plate and UHMWPE liner inter locking**

	-AP-42,44.5,47,50.5,50.5,55.5 mm and ML-63,67,71,71,80,80 mm **Patella component- 5 sizes of patella component** **- Patella-XS(d=26&t=8),** **Patella-S(d=29&t=8.5),** **Patella-M(d=32&t=8.5),** **Patella-L(d=35&t=9),** **Patella-XL(d=38&t=9.5)**		**previously released Druacon Total Knee System, as well as the previously released Triathlon PS femoral component in situations where replacement of the articular surface of the patella is required. The Triathlon CR Total Knee System is intended to accommodate the posterior circulate ligament (PCL) if it is present.** **Components:** ➢ **Femoral Component Tibial Implant** ➢ **Tibial Implant** ➢ **Metal backed tibial component** ➢ **Patellar component**		**system**
ROM	**0º to 135º**	**0º to 115º**	➢ **Duracon knee system- 0º to 130º**	**NexGen** ➢ **CR knee system-0º to**	**Similar with predicate**

			➢ Triathlon™ (CR) Total Knee System-0º to 150º	120º ➢ CR-flex knee system-0º to 155º	device range
Materials	➢ Femoral- Cast CoCr to ISO 5832-4 / ASTM F75 ➢ Tibia- Ti-6Al-4V ASTM F.136-ISO 5832/3 ➢ UHMWPE insert- GUR 1020 ➢ Patella component- GUR 1020	➢ Femoral- Cast CoCr to ISO 5832-4 / ASTM F75 ➢ Tibia- Ti-6Al-4V ASTM F.136-ISO 5832/3 ➢ UHMWPE insert- GUR 1020 ➢ Patella component- GUR 1020	➢ Femoral Implant CoCrMo ➢ Metal-Backed Tibial Components; ➢ Tibial tray-CoCrMo ➢ Tibial Insert-UHMWPE with CoCrMo locking wire ➢ All Polymer Patellar Component-(UHMWPE)	➢ Femoral- Cast CoCr to ISO 5832-4 / ASTM F75 ➢ Tibia- Ti-6Al-4V ASTM F.136-ISO 5832/3 ➢ UHMWPE insert- GUR 1020 ➢ Patella component- GUR 1020	**Similar with predicate device**
Principle of Operation	**Cemented use fixed bearing design**	**Cemented use fixed bearing design**	**Same and Duracon knee system used with and without cement**	**Cemented use fixed bearing design**	**Similar with predicate device**

Sterility	**Gamma sterilization**	**Gamma sterilization**	**Gamma sterilization**	**Gamma sterilization**	**Similar with predicate device**