

2. 510(k) SUMMARY

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, CA 95762

510(k) Contact: Matthew M. Hull, RAC
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Date Prepared: 20 December 2013

Trade Name: VitalitE Tibial Insert & Patellar Components

Common Name: Total Knee Arthroplasty System

Classification Name: Knee joint patellofemorotibial Polymer/metal/polymer semi-constrained cemented prosthesis is a Class 2 device per 21 CFR 888.3560 (Product Code JWH/OIY)

Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3565 (Product Code MBH)

Device Description:

The VitalitE Tibial Insert is a vitamin E version of the UHMWPE tibial insert that has been a component of both the Consensus Knee System (CKS) and the Consensus Revision Knee System (RKS). The new insert still serves as the gliding surface between the metallic femoral component and the metallic tibial base plate of these knee systems. The new VitalitE insert will also be available in a cruciate retaining (CR) or ultra-congruent/ PCL substituting designs in sizes 0 through 6 and in thicknesses from 10 to 22 mm. The proprietary locking mechanism design on the underside of the insert will remain unchanged. The only difference will be the vitamin E additive in the UHMWPE which is α -tocopherol. This is the exact same polymer that is used in the Consensus VitalitE Acetabular insert but with a slightly lower radiation dose. Consensus will also offer our current CKS all-poly patellae in the new vitamin E UHMWPE material. This includes both the round and oval configurations with either a 7.5 mm or 10 mm thickness.

Indications for Use:

When used with the components of the Consensus Knee System:

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

- A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
- B. Failed osteotomy or unicompartmental replacements.
- C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
- D. The non-porous (uncoated and coated with CoCr beads without Titanium) components may only be used with cement.
- E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.

When used as a component of the Consensus Revision Knee System:

The Consensus® Revision Knee System is designed as a system and is only intended to be used with compatible components of the Consensus® Knee System. The revision knee femoral and tibial components are intended for cemented use only.

The indications for use are:

- A. Primary intervention of rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
- B. Post-traumatic loss of joint configuration (particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy)
- C. Failed osteotomy or unicompartmental replacements.
- D. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
- E. The salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery
- F. Moderate valgus, varus, or flexion deformities

Substantial Equivalence:

Technological Characteristics/ Substantial Equivalence:

The new VitalitE tibial insert is the exact same design as cleared for use with the Consensus Knee System in K932837, K953443 & K110950 and also with the Consensus Revision Knee in K100542 and is compatible with all of the metallic femoral and tibial components from those systems. The UHMWPE (GUR 1020) with a-tocopherol is the same polymer as that cleared in K130652 for the Consensus VitalitE Acetabular Insert with the exception of the slightly lower radiation dose. The use of Vitamin E infused UHMWPE tibial insert for knee systems has been cleared for use in DJO/ Encore systems via K091956 and K103223. The UHMWPE used in the current

Consensus tibial inserts is GUR 1050. The VitalitE inserts are cleaned, packaged, and sterilized using the same validated processes as the current inserts and will also have a 5 year shelf-life.

Non-Clinical Performance Data:

Non-clinical testing and analysis were provided, including bench testing, material characterization, and biocompatibility testing. Bench testing of the new insert material included wear testing of the worst case tibial insert, and anterior disassembly testing of the locking mechanism (push-out testing) on a range of various sizes and types of inserts.

All of the observed results indicate that the VitalitE Tibial Inserts and Patellas are substantially equivalent to devices currently marketed. Therefore, the devices are as safe, as effective, and perform at least as safely and effectively as legally marketed predicates.



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

July 14, 2014

Consensus Orthopedics, Incorporated
Mr. Matthew M. Hull
QS & RA Director
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

Re: K133919

Trade/Device Name: VitalitE Tibial Inserts & Patellar Components

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, MBH, OIY

Dated: June 10, 2014

Received: June 12, 2014

Dear Mr. Hull:

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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Lori A. Wiggins

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number: K133919

Device Name: VitalitE Tibial Inserts & Patellar Components

Indications for Use:

When used with the components of the Consensus Knee System:

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- C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
- D. The non-porous (uncoated and coated with CoCr beads without Titanium) components may only be used with cement.
- E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.

When used as a component of the Consensus Revision Knee System:

The Consensus® Revision Knee System is designed as a system and is only intended to be used with compatible components of the Consensus® Knee System. The revision knee femoral and tibial components are intended for cemented use only.

The indications for use are:

- A. Primary intervention of rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, and/or avascular necrosis of the femoral condyle.
- B. Post-traumatic loss of joint configuration (particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy)
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- D. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
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Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
 Division of Orthopedic Devices

