January 14, 2025

Shalby Advanced Technologies
Romil Sheth
QA/RA Manager
1115 Windfield Way
El Dorado Hills, California 95762

Re: K241180
Trade/Device Name: Consensus Knee System with TiNbN
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: November 18, 2024
Received: November 19, 2024

Dear Romil Sheth:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.01.14 00:18:23 -05'00'

For Lixin Liu, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241180

Device Name

Consensus Knee System with TiNbN

Indications for Use *(Describe)*

The indications for use are:

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, coated with CoCr beads without Titanium, and uncoated with a TiNbN overcoat) components may only be used with cement
E. The porous coated (CoCr beads with Titanium) components may be used with or without cement

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K241180

510(k) Summary

Prepared on: 2025-01-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shalby Advanced Technologies, Inc. dba Consensus Orthopedics
Applicant Address	1115 Windfield Way El Dorado Hills CA 95762 United States
Applicant Contact Telephone	+1 2134002624
Applicant Contact	Mr. Romil Sheth
Applicant Contact Email	rsheth@shalby.us

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Consensus Knee System with TiNbN
Common Name	Total knee prosthesis
Classification Name	prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
Regulation Number	21 CFR 888.3560
Product Code(s)	JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K110950, K001456	Consensus Knee System (CKS)	JWH, MBH
K182251, K122239	EVOLUTION NitrX Medial-Pivot Knee, Foundation, Foundation	JWH

Device Description Summary

21 CFR 807.92(a)(4)

The femoral implants are provided in left and right-side versions and designed to replicate the natural anatomy of the femur. They are available in a single variant only - CR, with sizes ranging from 1 to 6. The femoral implants have a RLP design, which offers surgeon an option for patients where a more minimal anatomic design is preferred. The femoral implants are manufactured using cast CoCrMo alloy (ASTM F75). A monolayer of TiNbN coating (thickness: 3 to 7 microns) is applied to the entire surface of the femoral implants.

The tibial baseplates are provided in left and right-side versions and designed to replicate the natural anatomy of the tibia. The tibial baseplates are available in three variants – holed, pegged, and pegless, with sizes ranging from 0 to 6. The tibial baseplates are manufactured using cast CoCrMo alloy (ASTM F75). A monolayer of TiNbN coating (thickness: 3 to 7 microns) is applied to the entire surface of the tibial baseplates.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The indications for use are:

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, coated with CoCr beads without Titanium, and uncoated with a TiNbN overcoat) components may only be used with cement

E. The porous coated (CoCr beads with Titanium) components may be used with or without cement

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices have the same intended use and indications for use as the predicate devices.

The subject devices have the same design, except the TiNbN coating, as the predicate devices. The dimensions and tolerances for the subject devices are same as the predicate devices. The subject devices use the same substrate material, same packaging, same sterilization method, and same shelf life as the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The subject devices have the same intended use, same indications for use, and similar technological characteristics as the predicate devices. The only difference in the technological characteristics is the application of the TiNbN coating on subject devices, whereas the predicate devices are uncoated.

The questions of safety and effectiveness regarding the TiNbN coating are whether it is biocompatible and whether it impacts (negatively) the articulating surface wear (femoral implant – tibial insert). These questions are also applicable to the predicate devices, therefore, the TiNbN coating does not raise different questions of safety and effectiveness.

The subject devices are manufactured using the same substrate material, cast CoCr (ASTM F75), as the predicate devices. The subject devices use the same manufacturing process (including manufacturing contact materials) as the predicate devices, except, the TiNbN coating step. DOT America, the company which performs the TiNbN coating step for the subject devices, has conducted exhaustive biocompatibility testing for the TiNbN coating on CoCr material (cytotoxicity, sensitization, irritation, acute systemic toxicity, and implantation). Therefore, based on the substrate material/manufacturing process equivalency between the subject and predicate devices and the biocompatibility testing data from DOT America for the TiNbN coating, the subject devices with the TiNbN coating are considered biologically safe.

The wear performance of the subject and predicate devices was evaluated under Mode 1 and Mode 3 conditions per ISO 14243-1. Based on the results of the wear testing, the subject devices have a superior wear resistance than the predicate devices under both Mode 1 and Mode 3 conditions.

Further, the following reference devices are TiNbN coated by DOT America:

Foundation, Foundation – PS, 3D-Knee (K122239)
EVOLUTION NitrX Medial-Pivot Knee (K182251)

Therefore, based on the above discussion, the subject devices are considered substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Following nonclinical testing/statements have been provided in this submission. The TiNbN coating testing/statements are performed by DOT America.
1) TiNbN coating testing/statements
o Chemistry
o Physical properties
 Coating thickness
 Roughness
o Mechanical properties
 Tensile bond strength
 Tensile shear strength
 Adhesive strength
 Micro Hardness
o Other testing/statements
 Figure_Liquid Contact Angle_TiNbN
 Statement_Fixture Point_TiNbN
 Test_Influence of PVD Coating on Base Material
 Test_Adhesive Strength of Bone Cement on PVD
 Statement_Artificial Aging_TiNbN
 Statement_MRI_TiNbN
2) Wear performance of the subject and predicate devices under Mode 1 and Mode 3 conditions
3) The following mechanical tests/analysis were leveraged from predicate devices. The predicate devices are identical to the subject

devices, except that the subject devices have the TiNbN coating on the surface. However, the TiNbN coating does not have any effect on these tests and hence, the testing performed of the predicate devices can be leveraged for the subject devices.
o Tibial Baseplate Fatigue Test
o Tibial Baseplate – Tibial Insert Locking Mechanism
o Range of Motion Analysis

The test reports, statements, and justification for using existing testing are attached to this section.

N/A

A significant number of tests were performed by DOT in support of ascertaining the safety and efficacy of the TiNbN coating. The wear performance of the subject and predicate devices was evaluated under Mode 1 and Mode 3 conditions per ISO 14243-1. Based on the results of the wear testing, the subject devices have a superior wear resistance than the predicate devices under both Mode 1 and Mode 3 conditions. The tibial baseplate fatigue test, tibial baseplate - tibial insert locking mechanism test, and range of motion analysis for the predicate devices are leveraged for the subject devices. Based on the nonclinical testing data, it can be concluded that the subject devices are at least as safe and effective as the predicate devices.