April 2, 2026

Shalby Advanced Technologies, Inc. Dba Consensus Orthopedics
Romil Sheth
QA & RA Manager
1115 Windfield Way
El Dorado Hills, California 95762

Re: K260796
Trade/Device Name: Tahoe Unicondylar Knee System with TiNbN Overcoat
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: March 11, 2026
Received: March 11, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

LIXIN LIU -S

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.*

510(k) Number *(if known)*
K260796

Device Name
Tahoe Unicondylar Knee System with TiNbN Overcoat

Indications for Use *(Describe)*
The Tahoe Unicondylar Knee System (TUKS) is designed as a system and is not intended for substitution of components from other systems. The indications for use are as follows:

Primary medial or lateral compartmental intervention of (1) primary non-inflammatory degenerative disease, including osteoarthritis, traumatic arthritis, or osteonecrosis; (2) post-traumatic degenerative disease; (3) varus or valgus deformities; and (4) damage due to previous surgical intervention when the opposite compartment is preserved and when the anterior cruciate, posterior cruciate, medial collateral, and lateral collateral ligaments are present and functional.

All TUKS implants (TiNbN coated and uncoated) are single use only and are intended for implantation only with bone 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.**

# 510(k) Summary

## 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: (213) 400-2624

Applicant Contact: Mr. Romil Sheth

Applicant Contact Email: rsheth@shalby.us

## Device Name (21 CFR 807.92(a)(2))

Device Trade Name: Tahoe Unicondylar Knee System with TiNbN Overcoat

Common Name: Unicompartmental Knee System

Classification Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

Regulation Number: 888.3520

Product Code(s): HSX

## Legally Marketed Predicate Devices (21 CFR 807.92(a)(3))

Primary Predicate #: K170344, Tahoe Unicondylar Knee System, Product Code HSX

Additional Predicate #: K241180, Consensus Knee System with TiNbN, Product Code JWH; K122239, Foundation, Foundation – PS, 3D-Knee, Product Code JWH; K182251, EVOLUTION NitrX Medial-Pivot Knee, Product Code JWH

## Device Description Summary (21 CFR 807.92(a)(4)):

The Tahoe Unicondylar Knee System (TUKS) is an unconstrained, round-on-flat, fixed bearing unicompartmental knee system designed to replace the medial or lateral compartments of the knee.

Femoral Component:

The femoral component is symmetric and comes in eight sizes (1-8). Its primary articular surface is spherical and highly polished to maximize wear performance. The femoral component employs a curved distal backside surface with posterior facet to conserve bone. The back side features two pegs and is grit blasted to enhance cement fixation. The femoral component is compatible with the existing/previously cleared TUKS tibial insert.

The femoral component is manufactured from cast CoCrMo (ASTM F75). A monolayer of TiNbN coating (thickness: 3 to 7 microns) is applied to the entire surface of the femoral component.

Tibial Component:

The tibial component includes two parts to be assembled at the time of surgery: a tibial baseplate and a tibial insert. The tibial component uses the existing/previously cleared TUKS tibial insert.

There is no change to the existing/previously cleared TUKS tibial insert. The tibial baseplate is asymmetric (it is provided in RM/LL and RL/LM variants) and comes in nine sizes (0-8). Its superior geometry includes a fully enclosed peripheral rim to allow encapsulation of the tibial insert, which forms the tibiofemoral bearing surface. Its backside surface features a keel and an angled peg, and is grit blasted to enhance cement fixation. When combined with the tibial insert (which comes in thicknesses 6-12mm), the tibial component thickness ranges from 8-14mm in 1mm increments. The insert is designed to lock into the baseplate at its anterior and posterior ends. The tibial baseplate-tibial insert locking mechanism is same as that of the existing/previously cleared TUKS uncoated tibial baseplate- tibial insert.

The tibial baseplate is manufactured from cast CoCrMo (ASTM F75) or wrought CoCrMo (ASTM F1537). A monolayer of TiNbN coating (thickness: 3 to 7 microns) is applied to the entire surface of the tibial baseplate.

**Intended Use/Indications for Use (21 CFR 807.92(a)(5))**

The Tahoe Unicondylar Knee System (TUKS) is designed as a system and is not intended for substitution of components from other systems. The indications for use are as follows:

Primary medial or lateral compartmental intervention of (1) primary non-inflammatory degenerative disease, including osteoarthritis, traumatic arthritis, or osteonecrosis; (2) post-traumatic degenerative disease; (3) varus or valgus deformities; and (4) damage due

to previous surgical intervention when the opposite compartment is preserved and when the anterior cruciate, posterior cruciate, medial collateral, and lateral collateral ligaments are present and functional.

All TUKS implants (TiNbN coated and uncoated) are single use only and are intended for implantation only with bone cement.

**Indications for Use Comparison (21 CFR 807.92(a)(5))**

The proposed device has the same intended use and indications for use as the predicate device.

**Technological Comparison (21 CFR 807.92(a)(6))**

The proposed device has the same design, except for the TiNbN coating, as the predicate device. The proposed device uses the same substrate material, same packaging, same sterilization method, and shelf life as the predicate device.

The questions of safety and effectiveness raised with the addition of TiNbN coating are whether it is biocompatible and whether it adversely impacts the articulating surface wear (femoral implant – tibial insert). These questions are also applicable for the predicate device, therefore, the addition of TiNbN coating does not raise different questions of safety and effectiveness for the proposed device.

Based on the substrate material/manufacturing process equivalency between the proposed and predicate devices and the biocompatibility testing data from DOT America for the TiNbN coating, the proposed device with the TiNbN coating are considered biologically safe.

Based on the literature review, information provided by DOT America to Shalby Advanced Technologies, Inc. and results of wear testing for Consensus Knee System with TiNbN which demonstrated that the application of TiNbN coating does not adversely affect wear performance in comparison to uncoated device, wear testing for the proposed device is deemed not necessary to establish safety and effectiveness.

The proposed device is considered substantially equivalent to the predicate device.

**Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b))**

No non-clinical or clinical tests were deemed necessary for the proposed device. The proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.