November 20, 2025

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

Re: K252846
Trade/Device Name: TaperSet™ Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO , JDI , OQG , OQI
Dated: September 5, 2025
Received: September 8, 2025

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,

RYAN TROMBETTA -S

For: Limin Sun, 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)*
K252846

Device Name
TaperSet™ Hip System

Indications for Use *(Describe)*
The indications for use for TaperSet™ Hip System are:

The TaperSet™ Hip System is designed for total hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System including the CS2™ Acetabular Cup System.

The indications for use are:
A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-union of proximal femoral neck fractures.
F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TaperSet™ hip stem is indicated for cementless use.

The Consensus acetabular cup components are intended for cemented or cementless use. The CS2 Ti plasma coated acetabular shell is intended for cementless use. The Consensus all-poly acetabular cup is intended for cemented use.

The intended use or indications for use of the TaperSet™ Hip System are similar to its original clearance K102399 except the removal of 'partial hip arthroplasty" as the DAA surgical technique is only applicable to the total hip system.

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: TaperSet™ Hip System

Common Name: Hip prosthesis

Classification Name:

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (primary)

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Hip joint metal/polymer semi-constrained cemented prosthesis.

Regulation Number: 888.3358 (primary), 888.3353, 888.3350

Product Code(s): LPH (Primary), LZO, JDI, OQG, OQI

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

Primary Predicate #: K141043

Additional Predicate #: K102399

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

Shalby Advanced Technologies, Inc. has created the DAA surgical technique for its cleared TaperSet™ Hip System including hip implants – TaperSet Femoral Stems™ and CS2™ Acetabular Components as well as other compatible components.

There have been no changes made to the TaperSet™ Femoral Stems and CS2™ Acetabular Components or any other compatible components from their previous clearances in developing the DAA surgical technique.

The TaperSet™ Femoral Stems are available in sizes ranging from 5 to 24mm in standard and 7mm lateralized neck options. The TaperSet™ Femoral Stems with Reduced Distal Profile (RDP) are available in sizes ranging from 10.5 to 24mm in standard and 7mm lateralized neck options. The femoral stems are manufactured from wrought or forged titanium alloy (Ti-6Al-4V), except the 5 and 6mm femoral stems which are manufactured from forged titanium alloy (Ti-6Al-4V) only, and the proximal portion is plasma sprayed with commercially pure titanium.

The CS2™ Acetabular Components include acetabular shells and mating liners. The acetabular shells and liners have matching circumferential scallops that rotationally secure the insert in the shell and allow for dialing the insert in a desired orientation. The shells with screw holes have anatomically placed holes, which accommodate optional screws for additional fixation. The shells are manufactured from titanium alloy (Ti-6Al-4V) and are porous coated with either commercially pure titanium sintered or diffusion bonded irregular beads or commercially pure titanium plasma spray. The acetabular shells coated with titanium irregular beads are available in six configurations (1) Hemispherical with three screw holes, (2) Hemispherical with eight to ten screw holes, (3) Hemispherical without screw holes, (4) Flared rim with three screw holes, (5) Flared rim with eight to ten screw holes, and (6) Flared rim without screw holes. The acetabular shells with titanium plasma spray are available in one configuration: hemispherical with three screw holes. The acetabular shells are available in sizes ranging from 42 to 68mm.

The CS2™ and CS2™ PLUS acetabular liners are manufactured from highly cross-linked UHMWPE or highly cross-linked UHMWPE blended with Vitamin-E (VitalitE). The CS2 acetabular liners made from highly cross-linked UHMWPE are available in two configurations: (1) Rimmed neutral and (2) Rimmed hooded. The CS2™ acetabular inserts made from VitalitE are available in four configurations: (1) Rimmed neutral, (2) Rimmed hooded, (3) Rimless neutral, and (4) Rimless hooded. The CS2™ PLUS acetabular inserts are designed with a +5mm lateralized offset and are available in two configurations: (1) Rimmed neutral and (2) Rimmed hooded.

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

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

There are no changes to the technological characteristics of each component in the subject total hip system because of the DAA surgical technique:

• Intended use/Indications for use

- Device dimensions or tolerances
- Material
- Manufacturing process
- Packaging
- Sterilization method
- Shelf life

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

Design Validation using Cadaveric Hips was conducted to ensure successful preparation of the acetabulum and femur and/or implantation of the subject total hip system using the DAA surgical technique and associated instruments.