May 1, 2025

United Orthopedic Corporation
Lois Ho
Regulatory Affairs Manager
No 57, Park Ave 2, Science Park
Hsinchu, 30075
Taiwan

Re: K242315
Trade/Device Name: Resolve Modular Revision Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO, KWY
Dated: August 5, 2024
Received: August 5, 2024

Dear Lois Ho:

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,

Limin Sun -S

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)*
K242315

Device Name
Resolve Modular Revision Hip Stem

Indications for Use *(Describe)*
1. Non-inflammatory degenerative joint disease Including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

This device is a single use implant and intended for cementless use only.

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

Traditional 510(k)

[as required by 21 CFR 807.92(c)]

Prepared by date: 2025-0501

Contact Details

Applicant Name	United Orthopedic Corporation
Applicant Address	No. 16, Luke 1st Rd. Luzhu Dist., Kaohsiung 82151 Taiwan
Applicant Contact Telephone	+88635773351
Applicant Contact	Ms. Lois Ho
Applicant Contact Email	lois.ho@unitedorthopedic.com

Device Name

Device Trade Name	Resolve Modular Revision Hip Stem
Common Name	Modular Femoral Stem
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulation Number	888.3353 888.3390
Product Codes	MEH, LZO, KWY

Predicate Device Information

510(k) Number	Predicate Trade Name
K090757	Arcos® Modular Femoral Revision System
K022549, K051363, K213129	Restoration® Modular System
K994126	MODULAR-PLUS REVISION STEM
K003237	U2 Hip Stem, HA/Ti plasma spray
K172251	UTS Stem, Ti plasma spray
K050262	U2 Acetabular Component
K110245	UTF Stem
K183312	Conformity Stem

Device Description Summary	Resolve Modular Revision Hip Stem is a modular stem optimized for femoral primary or revision surgery. It consists of three main components, (1) Resolve Proximal Component Resolve offers two types of proximal components, each available with either HA/Ti plasma spray or Ti plasma spray.

Type	With or without Hole	Coating	Device Name
1	With Hole	HA/Ti plasma spray	Resolve Proximal Component
	With Hole	Ti plasma spray	Resolve Proximal Component, Ti Plasma Spray
2	No Hole	HA/Ti plasma spray	Resolve Proximal Component, No Hole
	No Hole	Ti plasma spray	Resolve Proximal Component, Ti Plasma Spray, No Hole

(2) Resolve Distal Stem.

Resolve offers four types of distal stems including Taper Stem, Clothespin Stem, Clothespin With Hole Stem, and Interlocking Stems. The Clothespin With Hole Stem and Interlocking stem provide holes for additional Distal Interlocking Screw fixation. The Taper Stem does not have a coating. The other three types of stems are each available with either HA/Ti plasma spray or Ti plasma spray.

Type	With or without Hole	Coating	Device Name
1. Taper Stem	No Hole	Without Coating	Resolve Distal Stem, Taper
2. Clothespin Stem	No Hole	HA/Ti plasma spray	Resolve Distal Stem, Clothespin
	No Hole	Ti plasma spray	Resolve Distal Stem, Ti Plasma Spray, Clothespin
3. Clothespin With Hole Stem	With Hole	HA/Ti plasma spray	Resolve Distal Stem, Clothespin With Hole
	With Hole	Ti plasma spray	Resolve Distal Stem, Ti Plasma Spray, Clothespin With Hole
4. Interlocking Stem	With Hole	HA/Ti plasma spray	Resolve Distal Stem, Interlocking
	With Hole	Ti plasma spray	Resolve Distal Stem, Ti Plasma Spray, Interlocking

(3) Resolve Distal Interlocking Screw

It is used with Resolve Clothespin With Hole Stem and Interlocking stem to provide an extra distal fixation and prevent subsidence.

Resolve Modular Revision Hip Stem can be used with "United" metallic femoral heads (K994078, K022520, K111546, K122504, K152439, K162957, K221675) or ceramic femoral heads (K103497, K112463,

	K122185). - Resolve Proximal Component Resolve offers two types of proximal component, with hole and no hole. The hole type provides a hole design on the lateral side of the proximal component. Both types are manufactured from Ti-6Al-4V alloy that complied with ASTM F136. There are two types of coating at the distal part of the proximal component. The first type is plasma spray coated with dual coatings, CP Ti powder (ASTM F1580) for the first layer, and HA powder (ASTM F1185, ISO 13779-6) for the second layer. The second type is plasma spray coated with only CP Ti powder (ASTM F1580). There are also two types of offset design, standard offset and high offset. Resolve Proximal Component are available in various diameters and proximal body heights. - Resolve Distal Stem, Taper Resolve Distal Stem, Taper is manufactured from Ti-6Al-4V alloy that complied with ASTM F136. The surface is grit-blasted. Resolve Distal Stem, Taper offers two stem lengths and is available in various diameters. - Resolve Distal Stem, Clothespin Resolve Distal Stem, Clothespin offers two types of proximal component, with hole and no hole. It is manufactured from Ti-6Al-4V alloy that complied with ASTM F136. Two types of coating identical to Resolve Proximal Component, HA/Ti dual coating and Ti single coating. All types of Resolve Distal Stem, Clothespins are available in various diameters. - Resolve Distal Stem, Interlocking Resolve Distal Stem, Interlocking is manufactured from Ti-6Al-4V alloy that complied with ASTM F136. Two types of coating identical to Resolve Proximal Component, HA/Ti dual coating and Ti single coating. Both types have the hole design to be used with Resolve, Distal Interlocking Screw to provide an extra distal fixation and prevent subsidence. All types of Resolve Distal Stem, Interlocking are available in various diameters. - Resolve, Distal Interlocking Screw Resolve, Distal Interlocking Screw is manufactured from Ti-6Al-4V alloy that complied with ASTM F136. It is used with Resolve Clothespin With Hole Stem and Interlocking stem to provide an extra distal fixation and prevent subsidence. It is available in various lengths.
Intended Use/ Indications for Use	1. Non-inflammatory degenerative joint disease Including osteoarthritis and avascular necrosis. 2. Rheumatoid arthritis. 3. Correction of functional deformity.

	4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. 5. Revision of previously failed total hip arthroplasty. This device is a single use implant and intended for cementless use only.
Indications for Use Comparison	The indication for use of the subject device are similar to the predicate devices.
Technological Comparison	The Subject device fundamental scientific principles and technological characteristics, including: material and general design, are the same as, or similar to, the primary predicate and the chosen additional predicate/reference devices. Summary of the technological characteristics: - Applied anatomical sites, operating principles, and conditions of use are identical. - No new risks associated to the Subject device compared to those of the predicate devices. - Material are similar to the primary predicate. - Geometry and size: Most of the sizes of the Subject device are bracketed in size by the predicates, except for the diameter of Resolve Distal Stem, Taper and the length of Resolve, Distal Interlocking Screw. The worst-case of Resolve Distal Stem, Taper and Resolve, Distal Interlocking Screw have been demonstrated equivalent safety and effectiveness as compared to the predicate devices. - Sterilization: identical method as predicates. The technological characteristics of the Subject device are substantially equivalent to the predicate device(s).
Non-Clinical and/or Clinical Tests Summary & Conclusions	Based on the design rationale of the Subject device, the following tests were conducted to evaluate the safety and effectiveness of the subject device, and the test results indicated that this device is safe and effective. • Range of Motion (ISO 21535) • Pull-out Strength of Morse Taper (ISO 7206-10) • Neck Fatigue Test (ISO 7206-6) • Stem Fatigue Test combined with Disassembly Test (ISO 7206-4, ISO 7206-10) • Fretting Corrosion (ASTM F1875) • Torsional Testing of Resolve Proximal Screw (ASTM F543) • Mechanical Testing of Resolve Distal Interlocking Screw (ASTM F543) • Characterization of HA/Ti Plasma Spray Coating (FDA guidance "510(k) information needed for Hydroxyapatite Coated Orthopedic Implants") • Characterization of Ti Plasma Spray Coating (FDA guidance "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Post market Surveillance Requirements")

	• Usability Evaluation (BS EN 62366-1, FDA guidance "Content of Human Factors Information in Medical Device Marketing Submissions", "Applying Human Factors and Usability Engineering to Medical Devices.") • Bacteria endotoxin testing was conducted and met the endotoxin limit as specified in USP<l 61 > No clinical studies were required or provided. Based upon showing equivalence in the following aspects: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the Subject device has been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the Subject device is substantially equivalent to the legally marketed predicate devices.