May 22, 2025

Ortho Development® Corp.
Drew Weaver
Director of Regulatory Affairs
12187 S. Business Park Drive
Draper, Utah 84020

Re: K251052
Trade/Device Name: Trivicta® 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, LPH, LZO, KWL
Dated: April 3, 2025
Received: April 3, 2025

Dear Drew Weaver:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251052

Device Name
Trivicta® Hip Stem

Indications for Use *(Describe)*

This device is intended for use in total and hemi-hip arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis, and/or post traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

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.

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ORTHO DEVELOPMENT®

510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Name of the Sponsor:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020	
510(k) Contact:	Name: Position: Address: Telephone: Email:	Drew Weaver Director of Regulatory Affairs 12187 S. Business Park Drive Draper, UT 84020 USA (801) 553-9991 dweaver@orthodevelopment.com
Date Prepared:	May 21, 2025	
Submission Type:	Traditional	
Proprietary Name:	Trivicta® Hip Stem	
Common Name:	Uncemented Hip Prosthesis (Hydroxyapatite coated hip prosthesis)	
Product Code / Classification:	MEH	21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Associated Product Code(s) / Classification:	LPH	21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
	LZO	21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
	KWL	21 CFR 888.3360: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Device Class:	Class II	
Primary Predicate Device:	Ortho Development® Trivicta® (K233758)	
Reference Predicate Device:	DepuySynthes Actis DuoFix Hip Prosthesis (K150862)	

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1.0 Device Description:

The subject device is a set of smaller stems that extends the size range of the previously cleared Trivicta® stems (K233758).

Trivicta® is a single-piece, tapered, collared and non-collared, hydroxyapatite (HA) and sintered bead commercially pure (Cp) Titanium coated femoral hip stem designed for single use. The stem has a neck with a 12/14 trunnion taper for modular attachment to femoral heads.

Trivicta® is manufactured from titanium alloy and device fixation is achieved through uncemented press-fit in the medullary canal and through the use of biocompatible HA coating and porous sintered bead coating.

The size range of the subject device is: lengths (97-101mm), horizontal offsets (36-43mm), vertical offsets (27-29mm), resection angle of 41°, and neck angle of 132°. The stem is offered with both standard (STD) and extended (EXT) offsets and with and without a collar.

Trivicta® is compatible with the following Ortho Development® devices: CoCr Femoral Heads, Biolox Delta Ceramic Femoral Heads, Solitude™ Unipolar Head, Escalade Acetabular Cup System, Legend® Acetabular Liner, Escalade Legend® Acetabular Shell, and Tri-plus™ DCM Liner.

2.0 Indication for Use:

This device is intended for use in total and hemi-hip arthroplasty. The device is intended for uncemented, press-fit use only in cases of:

1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis, and/or post-traumatic arthritis.
2. Previously failed hip surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors, congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

3.0 Comparison of Technological Characteristic:

Trivicta is the same as the previously cleared predicate device Ortho Development Trivicta (K233758) in terms of indications for use, materials, fixation, taper/trunnion, neck angle, offsets, collar/collarless, packaging, and sterilization, and is substantially equivalent to DepuySynthes Actis (K150862) for stem sizes and lengths.

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4.0 Performance Data:

Sterilization

Trivicta is gamma radiation sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the ISO 11137.

Shelf Life

The packaging for Trivicta was validated in accordance with ISO 11607.

Biocompatibility

Trivicta's biocompatibility was established according to the requirements of ISO 10993-1 and found to be safe for its intended use.

Mechanical Testing

The following non-clinical mechanical tests and analyses were conducted on the subject device.

- Range of Motion Test (ISO 21535:2023)
- Neck Fatigue Test (ISO 7206-6:2013)
- Distal Stem Fatigue Test (ISO 7206-4:2010)
- Engineering analysis of impingement performance (ASTM F2582-20)

Clinical Testing

No clinical testing is required to establish the safety and effectiveness of Trivicta.

5.0 Substantial Equivalence Conclusion:

Verification and validation activities were conducted to establish the performance of Trivicta. The results of verification and validation activities demonstrate that Trivicta is safe and effective and performs as well as the legally marketed predicates.

Based on similarities in indication for use/intended use, technological characteristic, basic design, device material, and principle of operation, Trivicta is considered substantially equivalent to the previously cleared predicate devices.