



November 5, 2025

Waldemar Link GmbH & Co. KG  
% Terry Powell  
V. P. Regulatory Affairs  
LinkBio Corp.  
69 King Street  
Dover, New Jersey 07801

Re: K250375

Trade/Device Name: Allure Hip Stem and Intramedullary Plugs

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, LPH, OQG, KWY

Dated: September 26, 2025

Received: September 26, 2025

Dear Terry Powell:

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K250375

Device Name  
Allure Hip Stem and Intramedullary Plugs

### Indications for Use (Describe)

The Allure Hip Stems are intended to be used in total and partial (hemi-) hip arthroplasty to treat mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures. The Allure Hip Stems are intended for uncemented use only.

### Indications:

- Primary and secondary osteoarthritis
- Rheumatoid arthritis
- Correction of functional deformities
- Avascular necrosis
- Femoral neck fractures
- Revision surgeries

The Intramedullary Plugs are intended for use with cemented hip stem prostheses to prevent uncontrolled diffusion of bone cement within the medullary canal.

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.

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**510(k) Summary**

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**Date Prepared:** November 4, 2025

**Trade Name:** Allure Hip Stem and Intramedullary Plugs

**Common Name:** Total hip replacement system

**Classification Name:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR §888.3353, product codes MEH, LZO  
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. 21 CFR §888.3358, product codes LPH, OQG  
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR §888.3390, product code KWY

**Classification and Panel:** Class II, Orthopedic / 87

**Predicate Devices:** See table below.

Subject Device Components	Predicate Devices	510(k) Number
Allure Hip Stem	1. DePuy Orthopaedics, Actis DuoFix Hip Prosthesis [Primary Predicate]	K150862, K160907, K210581
	2. Stryker Orthopaedics, Insignia Hip Stem [Additional Predicate]	K211703, K220731
Intramedullary Plugs	1. United Orthopedic Corp. Cement Restrictor [Additional Predicate]	K152530

**Reason for Submission:** New Device System Components

<b>Device Description:</b>	<p>This submission includes the Allure Hip Stems for cementless use and Intramedullary (IM) Plugs for use with cemented hip stem prostheses. Therefore, they are not meant to be used together, but the Allure Stems and the IM Plugs (when used with LINK cemented hip stems) are both used with the same previously cleared LINK systems (Prosthesis Heads and Vario Cups, BiMobile Dual Mobility System, MobileLink Acetabular Cup System) to create hemi-hip or total hip arthroplasty constructs.</p> <p>The Allure Hip Stem is forged out of a Ti6Al4V alloy. The Prosthesis Stems are proximally equipped with a TiCaP (Titanium-plasma + Calcium Phosphate) coating while the distal tip features a microporous surface with a HX (Calcium Phosphate) coating. The implants are available in different sizes and neck designs, standard or lateralized version and collared or collarless neck, allowing an accurate anatomical match for each patient.</p> <p>The Allure Hip Stem is part of a mechanical reconstruction of the hip joint. The Allure Hip Stem forms a total hip arthroplasty (THA) when combined with a prosthesis head and an acetabular cup. Alternatively, a hemiarthroplasty (HA) is formed, when combined with the Vario-Cup System. The Hip Stem is intended for uncemented use.</p> <p>The Intramedullary Plugs are used in combination with cemented implant components.</p> <p>The Intramedullary Plugs are manufactured from ultrahigh molecular weight polyethylene (UHMWPE), and in sizes from 8 mm to 20 mm.</p>
<b>Indications for Use:</b>	<p>The Allure Hip Stems are intended to be used in total and partial (hemi-) hip arthroplasty to treat mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures. The Allure Hip Stems are intended for uncemented use only.</p> <p>Indications:</p> <ul style="list-style-type: none"> <li>- Primary and secondary osteoarthritis</li> <li>- Rheumatoid arthritis</li> <li>- Correction of functional deformities</li> <li>- Avascular necrosis</li> <li>- Femoral neck fractures</li> <li>- Revision surgeries</li> </ul> <p>The Intramedullary Plugs are intended for use with cemented hip stem prostheses to prevent uncontrolled diffusion of bone cement within the medullary canal.</p>
<b>Comparison to Predicate Device:</b>	<p>The Allure Hip Stem is substantially equivalent to the predicate stems in that all have similar indications, design, geometry, coating, materials and mechanical safety. The subject device and primary predicate differ with regard to their proximal Titanium coatings (the primary predicate stem uses sintered titanium beads, while the subject stem uses plasma-sprayed titanium). Titanium plasma spray is a common process for titanium coatings on orthopedic implants and is also featured on the additional predicate stem. All devices are intended for uncemented use only.</p>

The subject Intramedullary (IM) Plugs and additional predicate cement restrictor device are made from the same material and have similar designs. They are used for implantation of cemented prostheses to avoid uncontrolled diffusion of the cement within the intramedullary canal.

**Non-Clinical Performance:**

Non-clinical performance testing and analysis were provided, including:

- Distal stem fatigue testing per ISO 7206-4
- Stem neck fatigue testing per ISO 7206-6
- Range of Motion (ROM) evaluation per ISO 21535
- Engineering analysis of fretting corrosion performance
- Engineering analysis of impingement performance
- Coating Characterization
- Intramedullary (IM) Plug verification testing
- Biocompatibility evaluation per ISO 10993
- Sterilization testing (packaging simulation) per ASTM D4169

The results of non-clinical performance testing demonstrate that the devices are as safe and effective as the predicate devices, and therefore Substantially Equivalent.

**Clinical Performance:**

Clinical performance testing was not required to demonstrate the substantial equivalence of this device.

- Clinical Evidence
  - o Clinical evidence of the subject Intramedullary (IM) Plug from outside United States (OUS) use has been provided to support its safety and effectiveness.

**Conclusion:**

The subject devices are substantially equivalent to the predicate devices identified in this premarket notification. Technological differences between the subject and predicate devices do not raise new questions of safety or effectiveness, and established non-clinical testing and evaluation methods provide assurance of substantially equivalent performance characteristics.