July 20, 2022

Waldemar Link GmbH & Co. KG
℅ Mateusz Leszczak
Regulatory Affairs Manager
LinkBio Corp.
69 King Street
Dover, New Jersey 07801

Re: K221794
Trade/Device Name: Vario-Cup System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: June 21, 2022
Received: June 21, 2022

Dear Mateusz Leszczak:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*
K221794

Device Name
Vario-Cup System

Indications for Use *(Describe)*

Mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures.

Femoral neck fractures.

Correction of functional deformities.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

**510(k) Submitter:**

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**Date Prepared:**

July 18, 2022

**Trade Name:**

Vario-Cup System

**Common Name:**

Hemi-Hip Prosthesis

**Classification Name:**

Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented or Uncemented; 21 CFR §888.3390, product code KWY

**Classification and Panel:**

Class II, Orthopedic / 87

**Predicate Devices:**

Waldemar Link GmbH & Co. KG. ENDOPROSTHESIS SYSTEM, VARIO-HEAD. K781735 [Primary Predicate]

AESCULAP, INC. AESCULAP BIPOLAR ACETABULAR CUP. K060707 [Additional Predicate]

Waldemar Link GmbH & Co. KG. *LINK*® MEGASYSTEM-C®. K151008 [Reference Device]

**Device Description:**

The Vario-Cup System consists of an UHMWPE component encased in an ultra-smooth polished EndoDur (CoCrMo) outer metal casing, for articulation in the bony acetabulum. It is to be used in conjunction with femoral components of the LINK Total Hip Systems. The 22 mm inner diameter Vario-Cup Prostheses are available in outer diameters ranging from 39-43 mm in 1 mm increments. Vario-Cups are self-centering which provides for a functional view of their position in post-op X-rays. An anti-luxation feature resists dislocation: an UHMWPE Safety Ring is placed in a groove at the

entrance of the polyethylene insert after assembly of Vario-Cup and femoral components.

**Indications for Use:**

Mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures.

Femoral neck fractures.

Correction of functional deformities.

**Comparison to Predicate Device:**

The additional 22mm Vario-Cup devices have the same intended use as the predicate devices and use materials identical to those used in the primary predicate ENDOPROSTHESIS SYSTEM, VARIO-HEAD K781735. The design of the subject and primary predicate devices has the same technological characteristics except: the subject device sizes are used with 22 mm heads and incorporate the anti-luxation safety ring, a design feature found in the 28 mm and 32 mm predicate devices but not the 24 mm predicate device variants.

The subject 22mm Vario-Cup devices are also similar to the additional predicate AESCULAP BIPOLAR ACETABULAR CUP K060707, which is also a dual mobility system and consists of a highly polished Cobalt Chrome alloy (CoCrMo) shell and a UHMWPE insert offered to fit either 22mm or 28mm heads. Both the Vario-Cup and AESCULAP BIPOLAR ACETABULAR systems are self-centering, and both feature a polyethylene locking ring.

The Vario-Cup Indications for Use are more specific than the original Primary Predicate K781735, and are consistent with similar contemporary predicate devices i.e. K060707.

The performance testing and analysis is sufficient to demonstrate that the subject and predicate devices are substantially equivalent with regard to design. Any difference between the subject and predicate device does not change the intended use or fundamental scientific technology.

**Performance Data:**

**Non-Clinical Performance and Conclusions:**
The following performance testing and analysis were performed to demonstrate that the 22 mm Vario-Cup System performs as intended and is substantially equivalent to the identified predicate devices:

- Material Characterization
- Disassembly Analysis
- Range of Motion Analysis
- Material Wear Analysis

The results of non-clinical performance testing and analysis demonstrate that the device is as safe, as effective, and substantially equivalent to the predicate devices.

**Clinical Performance and Conclusions:**
There was no clinical performance testing required for this device.

**Conclusion:**

The subject device 22 mm Vario-Cup System is substantially equivalent to the predicate devices identified in this premarket notification.