April 14, 2026

Adelina Chiaravalloti
Director, Regulatory Affairs and Clinical Evaluation
Corcym S.r.l.
Via Crescentino Sn, Saluggia, VC 13040 ITA

Re: K260498
Trade/Device Name: TriMemo™ Semirigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: February 13, 2026
Received: February 13, 2026

Dear Adelina Chiaravalloti:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JULIE B. MACKEL -S
Digitally signed by JULIE B. MACKEL -S
Date: 2026.04.14 10:03:54 -04'00'

For

Jennifer Kevit, PhD
Acting Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K260498

Device Name
TriMemo SemiRigid Annuloplasty Ring

Indications for Use *(Describe)*
TriMemo is indicated for use in patients suffering from congenital or acquired tricuspid insufficiencies or steno-insufficiencies with dilatation and/or deformation of the tricuspid annulus.

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

Prepared on: 2026-04-03

Contact Details

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Correspondent Contact Telephone	+393427516807
Correspondent Contact	Mrs. Adelina Chiaravalloti
Correspondent Contact Email	adelina.chiaravalloti@corcym.com

Device Name

Device Trade Name	TriMemo™ SEMIRIGID ANNULOPLASTY RING
Common Name	Annuloplasty ring
Classification Name	Ring, Annuloplasty
Regulation Number	870.3800
Product Code(s)	KRH

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K103520	CARPENTIER-EDWARDS PHYSIO TRICUSPID ANNULOPLASTY RING, model 6200	KRH

Device Description Summary

TriMemo™ is a semirigid annuloplasty ring intended to restore the proper tricuspid valve leaflet coaptation and valve function by reshaping the tricuspid annulus.
The TriMemo consists of an inner electropolished Nitinol core embedded in a sewing ring of silicone and knitted with polyester (PET) fabric. The fabric is coated with Carbofilm™ coating, a thin layer of turbostratic carbon. The ring has an open 3D shape and modular flexibility which adapt to the annulus tridimensional anatomy and movements, with the highest stiffness in the posterior portion, that gradually decreases toward the anterior and septal ends. The cuff has a white guideline to identify the suturable portion, two commissural markers for the correct positioning in the annulus and two markers close to the open ends, that indicate the end of the suturable portion.
TriMemo is available in 6 sizes of increasing dimension starting from size 26 to size 36 with 2 mm steps. The device is supplied as a sterile (steam sterilization) and non-pyrogenic ring, for single-use only.
TriMemo exhibits a modular flexibility to comply with the three-dimensional annulus motion. The ring is stiffer in the posterior portion corresponding to the native valve dilated wall, and gradually flexible towards the ends that are open to avoid interference with the heart conduction system.

The core stiffness is calculated through a Finite Element Method and varies between the core posterior portion (rigid) and the two core ends (flexible), slightly increasing with the core size.

The ring mechanical strength in-plane and out-of-plane, and the suture pull-out test guarantee resistance to loading conditions higher than 3 times those occurring under in-vivo conditions. The TriMemo expected lifetime under continued function is at least 400 million cycles corresponding to a 10-year implant lifetime. In clinical use the device lifetime is affected by many patient factors and thus a definitive expected lifetime cannot be assured.
TriMemo shows high visibility through imaging techniques, for the whole device length.

Intended Use/Indications for Use

TriMemo is indicated for use in patients suffering from congenital or acquired tricuspid insufficiencies or steno-insufficiencies with dilatation and/or deformation of the tricuspid annulus.

Indications for Use Comparison

Corcym TriMemo	Edwards PHYSIO (K103520)	Comparison Notes
TriMemo is indicated for use in patients suffering from congenital or acquired tricuspid insufficiencies or stenoinsufficiencies with dilatation and/or deformation of the tricuspid annulus.	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is intended for use in patients with tricuspid valvular insufficiency. It is intended to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.	Both devices are indicated for patients with tricuspid valvular insufficiency; the additional information on "congenital or acquired" insufficiency included in TriMemo is only meant to specify that both types of insufficiencies are included. The "stenoinsufficiencies" included in TriMemo is a type of insufficiency (where patients affected by insufficiency have also a partial stenosis of the valve). Therefore, the generic indication "insufficiency" in the Physio IFU also includes the indication for patient with stenoinsufficiencies: the aim of both rings is to correct the insufficiency of the tricuspid valve. **No substantive differences are identified; differences are merely in wording, which do not alter the substantial equivalence of the indications for use statements**
TriMemo is indicated for use in patients suffering from congenital or acquired tricuspid insufficiencies or stenoinsufficiencies with dilatation and/or deformation of the tricuspid annulus.	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is intended for use in patients with tricuspid valvular insufficiency. It is intended to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.	Although description in Trimemo indications for use is concise, TriMemo, as an annuloplasty device, shares the same indications for use of Physio, aiming to restore the anatomical and functional geometry of the annulus, thus leading to an improved leaflet coaptation (as specified in Physio) and reducing functional regurgitation associated with annular dilation and/or deformation → both devices act via annular remodeling and stabilization thus preventing further dilation, and - as consequence of annular

Corcym TriMemo	Edwards PHYSIO (K103520)	Comparison Notes
		remodeling and stabilization - via leaflet coaptation enhancement. **No substantive differences are identified; differences are merely in wording, which do not affect the substantial equivalence of the indications for use statements**

Based on the comparison table above, the indications for use statement for TriMemo are substantially equivalent to those of the predicate device.

Technological Comparison

The analysis conducted regarding TriMemo and Physio technological characteristics has considered:

- Design: both are open semi-rigid open rings
- Materials: both have metallic cores covered with polyester cloth.
- Both rings are supplied sterile (steam sterilized) and non-pyrogenic, for single-use only.
- Both rings are provided on a holder, in a double-sealed packaging.
- Both rings have a 5-years shelf life
- The accessories used for allowing implantation are sizers, corresponding to each ring size, and a handle(s for TriMemo device) provided non-sterile. The accessories are packaged seperately, provided non-sterile and must be cleaned and sterilized before each use.

However, some technological differences have been identified:

- Slight design and shape differences - not raising different questions of safety and effectiveness, TriMemo design is based on other implantable medical devices and it is not an innovative one;
- Materials - even if the overall characteristics of device and packaging materials are the same, the existing differences do not raise any new questions of safety and effectiveness since TriMemo materials are already commonly used for Annuloplasty rings and they are not innovative materials.

Corcym decided to use Memo 4D Semirigid Annuloplasty Ring (K230318) as Reference device, for supporting the appropriate scientific methods used for characterizing the new device, based on similarities in terms of design, materials, packaging and manufacturing process.
The testing on TriMemo, performed according to FDA guidance and recognized standards, evaluated substantial equivalence to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Based on the differences between TriMemo and the Predicate and Reference Devices, the following nonclinical Performance tests were specifically performed on TriMemo device confirming that there are substantially equivalent safety and effectiveness outcomes:

- Computational stress/strain Analysis as per FDA "Guidance for Annuloplasty Rings 510(k) Submissions" and "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol" following ISO 5910 and ASME V&V 40-2018;
- Verifications of mechanical characteristics of the device as per FDA "Guidance for Annuloplasty Rings 510(k) Submissions" and mechanical characterization of the PET fabric;

- Suture pull-out test as per FDA "Guidance for Annuloplasty Rings 510(k) Submissions";
- Fatigue testing as per FDA Guidance "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol" following ISO 5910
- MRI compatibility testing, following "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" and technical standards ASTM F2052-21, ASTM F2213-17, ASTM F2182-19e2, ASTM F2119-24, ASTM F2503-23e1;
- Usability Summative evaluation, following FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices".

Additionally:

- sterilization validation was performed according to appropriate FDA guidances ("Guidance for Annuloplasty Rings 510(k) Submissions", "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") and technical standards ISO 17665:2024, ISO-11138-1:2017, ISO-11138-3:2017, ISO 11737-2:2019, USP current ed. <71>, ANSI/AAMI ST72:2019, USP current ed. <161>, USP current ed. <85>;
- packaging validation was performed at t=0 (after environmental conditioning as per ASTM D4332:2022 and simulated distribution as per ASTM D4169:2024 - revision 2024 not FDA recognized) and after 5 years of acelerated ageing (ASTM F1980:2016(R2021)) by visually inspecting the devices as per ASTM F1886/F1886M:2016(R2024) and testing testing the sterile barrier integrity by seal strenght (ASTM F88 /F88M:2023) and bubble leak (ASTM F2096:2011(R2019)).

As results of the nonclinical tests performed, TriMemo has proven to withstand loading condition 3 times higher than those occurred under in-vivo conditions without any damages or ring shape alterations; the suture retention test was passed since all samples shown a value above the acceptance criteria; the device maintains its structural integrity for a minimum of 400 million cycles under simulated physiological flow, passed all non-clinical testing for hazards in MRI environment and the summative user evaluation. Based on the outcome of performance testing and validation conducted, TriMemo Semirigid Annuloplasty Ring is considered to be substantially equivalent to the predicate device, since they have the same intended use; the technological differences - supported by the reference device and the tests conducted - do not raise different questions of safety and effectiveness.