



June 18, 2026

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

Re: K261707

Trade/Device Name: MEMO 4D Curve™ Semirigid mitral annuloplasty ring  
Regulation Number: 21 CFR 870.3800  
Regulation Name: Annuloplasty Ring  
Regulatory Class: Class II  
Product Code: KRH  
Dated: May 22, 2026  
Received: May 22, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**JULIE B.**

Digitally signed by  
JULIE B. MACKEL -S

For **MACKEL -S**

Date: 2026.06.18  
22:18:48 -04'00'

Jennifer Kevit, PhD

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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261707

?

Please provide the device trade name(s).

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MEMO 4D Curve™ Semirigid mitral annuloplasty ring

Please provide your Indications for Use below.

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MEMO 4D Curve is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and/or deformation of the mitral annulus.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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## 510(k) Summary

In Accordance with 21 CFR 807.92

**510(k) Number: K261707**

Date Prepared: 2026-06-17

### I. Contact Details — 21 CFR 807.92(a)(1)

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<b>Applicant Name:</b>	Corcym S.r.l.
<b>Applicant Address:</b>	Via Crescentino sn Saluggia VC 13040 Italy
<b>Applicant Contact Tel.:</b>	+393499345991
<b>Correspondent Name:</b>	Corcym S.r.l.
<b>Correspondent Address:</b>	Via Crescentino sn Saluggia VC 13040 Italy
<b>Correspondent Contact Tel.:</b>	+393427516807
<b>Correspondent Contact:</b>	Mrs. Adelina Chiaravalloti
<b>Correspondent Email:</b>	adelina.chiaravalloti@corcym.com

### II. Device Name — 21 CFR 807.92(a)(2)

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<b>Device Trade Name:</b>	MEMO 4D Curve™ Semirigid mitral annuloplasty ring
<b>Common Name:</b>	Annuloplasty ring
<b>Classification Name:</b>	Ring, Annuloplasty
<b>Regulation Number:</b>	870.3800
<b>Product Code(s):</b>	KRH

### III. Legally Marketed Predicate Devices — 21 CFR 807.92(a)(3)

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<b>Predicate #:</b>	K230318
<b>Predicate Trade Name:</b>	Memo 4D Semirigid Annuloplasty Ring
<b>Product Code:</b>	KRH

### IV. Device Description Summary — 21 CFR 807.92(a)(4)

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MEMO 4D Curve™ is a semirigid open mitral annuloplasty ring intended to restore the proper mitral valve leaflet coaptation and valve function by reshaping the mitral annulus.

The MEMO 4D Curve includes a semirigid metallic core made of superelastic Nitinol alloy, a silicone elastomer enclosing the core and a knitted polyester fabric covered with Carbofilm™, sewed with a PET thread covered with Carbofilm™. The choice of device materials and configuration have the aim to ensure its biocompatibility and hemocompatibility. The ring has

an open 3D shape and modular flexibility to comply with the three-dimensional annulus motion: rigid in the portion corresponding to the posterior leaflet, and gradually more flexible towards the ends. The ring has, on one side, a white suture guide to identify the suturable portion and two commissural markers and a mid-line posterior marker for the alignment to the annulus.

Memo 4D Curve is available in 10 sizes of increasing dimension starting from size 24 to size 42 with 2 mm steps. Rings from size 24 to size 32 are flat, while the largest sizes (from 34 to 42) show a 3D shape (out-of-plane). The device is supplied as a sterile (steam sterilization) and non-pyrogenic ring, for single-use only.

MEMO 4D Curve exhibits modular flexibility to comply with the three-dimensional annulus motion. The ring is stiffer (low flexibility) in the posterior portion corresponding to the native valve dilated wall, and gradually flexible towards the ends. The ring is open in correspondence of the aorto-mitral continuity. The ring stiffness is mainly due to the Nitinol core, while the stiffness of the silicone and fabric are negligible. 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 MEMO 4D Curve 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.

Memo 4D Curve shows high visibility through imaging techniques for the whole device length.

## **V. Intended Use/Indications for Use — 21 CFR 807.92(a)(5)**

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MEMO 4D Curve is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and/or deformation of the mitral annulus.

*MEMO 4D Curve indications for use are the same as the Predicate Device Memo 4D Semirigid Annuloplasty Ring, owned by Corcym and cleared by FDA as K230318.*

## **VI. Technological Comparison — 21 CFR 807.92(a)(6)**

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The subject and the predicate device are based on the following same technological elements and the slight differences do not raise different questions of safety and effectiveness:

- Design: both are semi-rigid rings, made by a Nitinol core, a silicone elastomer enclosing the core and a knitted polyester fabric covered with Carbofilm™;
- Materials: same materials, with the exception of the ReChord System (only present on Memo 4D); the PET fabric material is the same between the devices and it differs exclusively for texturing and tubular diameter.
- Both rings are supplied sterile (steam sterilized) and non-pyrogenic, for single-use only;

- The rings are provided with the same packaging, with the exception of the adhesive blend of the Tyvek;
- Both rings have a 5-years shelf life;
- The same accessories are used for allowing implantation (sizers, corresponding to each ring size, and handles, provided non-sterile).

However, some technological differences have been identified:

- Slight design and shape differences - MEMO 4D Curve is an open ring. The potential risks coming out from these differences are addressed by testing performed according to well-established methods;
- Slight materials differences, described above - the potential risks coming out from these differences are addressed by testing performed according to well-established methods.

## **VII. Non-Clinical and/or Clinical Tests Summary & Conclusions — 21 CFR 807.92(b)**

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The testing and evaluations supporting the differences between MEMO 4D Curve and the Predicate Device, performed according to well-established methods, evaluated substantial equivalence of MEMO 4D Curve to the predicate. Based on the risk analysis summary, the following testing were performed:

- Computational Structural Analysis (Finite Element Analysis) as per ISO 5910 and ASME V&V 40-2018 (FDA "Guidance for Annuloplasty Rings 510(k) Submissions" and "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol");
- Mechanical Resistance testing on the device to ensure that the structural failure will only occur at loads greater than those experienced in vivo (and FDA "Guidance for Annuloplasty Rings 510(k) Submissions") and Mechanical characterization of PET fabric;
- Suture pull-out test to determine fabric strength in the annuloplasty ring and to ensure fabric sewing cuff is capable of retaining the suture in the heart annulus as per FDA "Guidance for Annuloplasty Rings 510(k) Submissions";
- Fatigue testing as per ISO 5910 (and FDA Guidance "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol");
- Usability Summative evaluation, following FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices";
- MEMO 4D Curve adopted the sterilization validation valid for the predicate device Memo 4D and performed according to appropriate FDA guidances 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 performed at t=0 (after environmental conditioning as per ASTM D4332:2022 and simulated distribution as per ASTM D4169:2024) and after 5 years of accelerated ageing (ASTM F1980:2016(R2021)) by visually inspecting the samples as per ASTM F1886/F1886M:2016(R2024) and testing the sterile barrier integrity by seal strength (ASTM F88/F88M:2023) and bubble leak (ASTM F2096:2011(R2019)).

Based on the outcome of the Design Control Activities, MEMO 4D Curve is considered to be substantially equivalent to the predicate device, since they have the same intended use and the technological differences do not raise different questions of safety and effectiveness.