April 7, 2023

Corcym S.r.l.
Silvia Contadini
Manager, Regulatory Affairs Europe and North America
Via Crescentino Sn
Saluggia, Vercelli 13040
Italy

Re: K230318
Trade/Device Name: Memo 3D Semirigid Annuloplasty Ring; Memo 3D ReChord Semirigid Annuloplasty Ring; Memo 4D Semirigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: January 30, 2023
Received: February 6, 2023

Dear Silvia Contadini:

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,

Jennifer Bastijanic -S

for Jaime Raben
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230318

Device Name
MEMO 3D Semirigid Annuloplasty Ring
MEMO 3D ReChord Semirigid Annuloplasty Ring
MEMO 4D Semirigid Annuloplasty Ring

Indications for Use *(Describe)*

Memo 3D device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

The use of the MEMO 3D ReChord device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

The use of the Memo 4D device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficient with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

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.

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K230318

I. Submitter Information

Submitter: **Corcym S.r.l.**
Via Crescentino, sn
13040 Saluggia (VC)
ITALY

Contact Person: Silvia Contadini
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Tel: +39 349 9345991
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Date Prepared: January 31st, 2023

II. Device Name and Classification

Proprietary Name[1]:	MEMO 3D Semirigid Annuloplasty Ring MEMO 3D ReChord Semirigid Annuloplasty Ring MEMO 4D Semirigid Annuloplasty Ring
Common/Usual Name:	Ring, Annuloplasty
Classification Name:	Annuloplasty Ring
Regulation Number:	21 CFR 870.3800
Product Code:	KRH
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The MEMO 3D, MEMO 3D ReChord and MEMO 4D Semirigid Annuloplasty Rings are substantially equivalent to their cleared predicate device identified below. All devices have the same fundamental scientific technology and intended use:

510(k) Number:	K071327, K142221, K180411
Proprietary Name:	MEMO 3D Semirigid Annuloplasty Ring MEMO 3D ReChord Semirigid Annuloplasty Ring

[1] The subject and predicate devices differ for the following:
- Different alternative suppliers of raw material of PET fabric;
- Different alternative suppliers of raw material of PET suture thread;
- Different alternative sewing path of the final assembly of the device.

	MEMO 4D Semirigid Annuloplasty Ring
Common/Usual Name:	Ring, Annuloplasty
Classification Name:	Annuloplasty Ring
Regulation Number:	21 CFR 870.3800
Product Code:	KRH
Classification:	Class II
Classification Panel:	Cardiovascular

IV. Device Description

Like their predicate devices, the subject MEMO 3D, MEMO 3D ReChord and MEMO 4D Semirigid Annuloplasty Rings are supplied as sterile, non-pyrogenic ring pre-mounted on disposable holders.

Both the predicate and subject devices are manufactured by embedding a superelastic metallic alloy inner core with medical grade silicone.
The resulting silicone sheath around the inner core is then encased within a tubular knitted fabric coated with a thin layer of turbostratic carbon (Carbofilm™). The fabric is then sewn along its length with a Carbofilm™ coated polyester thread.

Both the predicate and subject devices MEMO 3D ReChord and MEMO 4D Semirigid Annuloplasty Rings feature a fully removable system (i.e., the ReChord System) in the posterior curve of the annuloplasty ring, composed by a series of loops made by a single piece of yellow surgical thread retained in place by a single piece of blue surgical thread.
The ReChord System is designed to provide a temporary reference element to facilitate the sizing of the artificial chord length at the annular plane level when performing replacement of mitral chordae tendineae in concomitance with the implant of the annuloplasty ring.

The MEMO 3D and MEMO 3D ReChord Annuloplasty Rings are manufactured in 8 different sizes, from 24 to 38 mm, with 2 mm increments.

The MEMO 4D Annuloplasty Ring is manufactured in 10 different sizes, from 24 to 42 mm, with 2 mm increments.

A complete set of accessories is available separately to properly size the annulus and implant the MEMO 3D, MEMO 3D ReChord and MEMO 4D annuloplasty ring.

V. Indications for Use

Memo 3D device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the

annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

The use of the MEMO 3D ReChord device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficiencies with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

The use of the Memo 4D device is indicated for use in patients suffering from congenital or acquired mitral insufficiencies or steno-insufficient with dilatation and deformation of the mitral annulus. Type I insufficiencies, with no manifest lesions in the subvalvular apparatus, can be treated with the implant of the annuloplasty ring on its own. For type II insufficiencies, characterised by valve prolapse sustained by elongation/ breakage of the chordae tendineae and papillary muscles, and type III insufficiencies, characterised by partially immobilised leaflets due to the fusion/hypertrophy of the chordae tendineae, the device implantation must be accompanied by corrective valvuloplasty.

The subject devices have the same indications for use of the predicate devices.

VI. Substantial Equivalence Discussion

The subject and the predicate devices have the following common characteristics:

- Intended use and indications for use;
- Raw materials;
- Technological characteristics and design;
- Labeling;
- Packaging method;
- Sterilization method;

The following differences exist between the subject and the predicate devices:

- Different alternative suppliers of raw material of PET fabric;
- Different alternative suppliers of raw material of PET suture thread;
- Different alternative sewing path of the final assembly of the device.

VII. Non-Clinical Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence:

- Biocompatibility testing;
- Mechanical characterization of the PET fabric supplied by the alternative supplier;
- Mechanical characterization of the PET suture thread supplied by the alternative supplier and the alternative sewing path;
- Mechanical testing of the final device manufactured with PET fabric and PET suture thread supplied by alternative suppliers and with the alternative sewing path;
- Quality control testing performed to evaluate the Carbofilm coating on the PET fabric and on the PET suture thread supplied by the alternative suppliers;
- LAL test performed to evaluate the endotoxin contamination on the PET fabric and PET suture thread supplied by alternative suppliers and on final devices manufactured with these materials.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the subject devices, as the indications for use are equivalent to those of their predicate devices (K071327, K142221, K180411). The non-clinical testing referred to in this submission supports the substantial equivalence of these devices.

IX. Statement of Substantial Equivalence

The MEMO 3D, MEMO 3D ReChord and MEMO 4D Semirigid Annuloplasty Ring manufactured with the fabric and suture thread supplied by alternative suppliers and with the modified final assembly sewing path have been demonstrated to be substantially equivalent to the legally marketed predicate device, in terms of intended use and technological characteristics.