March 16, 2018

Sorin Group Italia S.r.l.
Mr. Mauro Ercolani
Director, Regulatory Affairs
Via Crescentino sn
13040 Saluggia, VC, Italy

Re: K180411
Trade/Device Name: MEMO 4D Semirigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: February 13, 2018
Received: February 15, 2018

Dear Mr. Ercolani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180411

Device Name
MEMO 4D Semirigid Annuloplasty Ring

Indications for Use *(Describe)*

Memo 4D device is intended for correction of mitral insufficiencies or steno-insufficiencies.

The use of the Memo 4D device is indicated for correction of congenital or acquired mitral 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.

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.

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510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: **K180411**

I. Submitter Information

Submitter:	**Sorin Group Italia S.r.l.** Via Crescentino, sn 13040 Saluggia (VC) ITALY
Contact Person:	Mauro Ercolani *Director, Regulatory Affairs* Tel: +39 0161 487 412 Fax: +39 0161 487 048 e-mail: mauro.ercolani@livanova.com
Date Prepared:	February 12, 2018

II. Device Name and Classification

Proprietary Name:	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 4D Semirigid Annuloplasty Ring is substantially equivalent to its cleared predicate device identified below. Both devices have the same fundamental scientific technology and intended use:

510(k) Number:	K142221
Proprietary Name:	MEMO 3D ReChord 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 its predicate device (the MEMO 3D ReChord Semirigid Annuloplasty Ring, K142221), the MEMO 4D Semirigid Annuloplasty Ring is supplied as a sterile, non-pyrogenic ring pre-mounted on a disposable holder.

Both the predicate and subject device 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 device 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 following changes were implemented:

The MEMO 4D is available in two new sizes: 40mm and 42mm.

The MEMO 4D features a larger silicone filler layer in the outer portion of the ring, intended to further facilitate ring suturing to the annulus.

A re-shaping of the MEMO 4D annuloplasty ring was implemented for sizes 34 to 42 mm. These sizes maintain the same core cross-sectional diameter and commissure-to-commissure dimension as the predicate MEMO 3D ReChord, but feature a gradual increase of the ring antero-posterior dimension and an out-of-plane “saddle” shape in the anterior ring portion. The ring re-shaping creates a differentiated design for the MEMO 4D with respect to the MEMO 3D ReChord. The design includes a rounder shaped implant to accommodate cases of excess leaflet tissue which may be indicative of degenerative mitral disease.

Minor design changes to the disposable holder to adapt to the modified ring shape and a new injection molding supplier for the holder were also introduced. The MEMO 4D packaging system was redesigned, introducing a double nested blister to replace the polysulfone containers used for the predicate MEMO 3D ReChord.

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

V. Indications for Use

MEMO 4D device is intended for correction of mitral insufficiencies or steno-insufficiencies.

The use of the MEMO 4D device is indicated for correction of congenital or acquired mitral 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.

VI. Substantial Equivalence Discussion

Table 1 presented in the following page compares the characteristics and features of the MEMO 4D to its predicate device.

Table 1 – Comparison with the predicate device

MEMO 4D characteristic / feature	Predicate Device 510(k) #	Predicate Device Proprietary Name	Device Equivalence
– Intended Use / Indications for use – Anatomical site for implantation – Target population	K142221	MEMO 3D ReChord Semirigid Annuloplasty Ring	The intended use and indications for use reported in the device labeling are the same between the MEMO 4D and the predicate device. The anatomical site for implantation and surgical access of the MEMO 4D are the same with respect to the predicate device. The differences between the predicate and the subject devices do not affect the disease / condition that the device is intended to treat or mitigate (i.e., mitral insufficiencies or steno-insufficiencies, with or without repair/replacement of chordae tendineae) or the target patient population (i.e., patients with repairable mitral valve via surgical approaches).
– Physical characteristics – Device design and materials			Both the MEMO 3D ReChord and the MEMO 4D are closed semirigid rings with variable flexibility (maximum flexibility in the posterior portion, gradually decreasing towards the anterior ring portion) used to restore proper leaflet coaptation and valve function by mechanically reshaping the mitral heart valve annulus. The MEMO 4D annuloplasty ring is identical to the predicate MEMO 3D ReChord device both in terms of implanted materials, device operating principle and mechanism of action.
– Product packaging and sterilization			The MEMO 4D sterile barrier consists of double nested polycarbonate blisters, whereas the sterile barrier of the predicate device consists of double nested polysulfone containers. The materials used for the MEMO 4D packaging are widely used for similar applications, and the sterile barrier has been qualified to maintain the device sterile over its stated shelf-life. The MEMO 4D is steam-sterilized using the same process in the same facility with respect to the predicate device.

VII. Non-Clinical Performance Data

Sorin Group Italia S.r.l. has conducted verification and validation testing of the MEMO 4D based on the risk analysis for the device.

Non-clinical testing included:

- computational stress analysis (FEA) and tensile strength testing;
- fatigue and durability testing;
- extraction tests for the ReChord System threads and disposable holder;
- biocompatibility testing;
- MRI compatibility testing;
- simulated distribution testing;
- package integrity and microbial barrier test after accelerated ageing;
- simulated use testing.

Suture pull-out, corrosion resistance, and long-term biocompatibility testing were previously conducted on the predicate device MEMO 3D ReChord and remain valid for the MEMO 4D due to similar materials, design and manufacturing technologies.

VIII. Clinical Performance Data

No clinical testing was conducted in support of the MEMO 4D Semirigid Annuloplasty Ring, as the indications for use are equivalent to those of its predicate device MEMO 3D ReChord. These types of devices have been on the market for many years with proven safety and efficacy of use. The non-clinical testing referred to in this submission supports the substantial equivalence of this device.

IX. Statement of Substantial Equivalence

The MEMO 4D Semirigid Annuloplasty Ring has been demonstrated as safe and effective for its intended use as the legally marketed predicate device.
With respect to intended use and technological characteristics, the MEMO 4D is substantially equivalent to the legally marketed predicate device.