July 1, 2020

Medtronic, Inc.
Lisa Corbin
Sr. Regulatory Affairs Specialist
1851 E. Deere Ave.
Santa Ana, California 92705

Re: K201449
Trade/Device Name: SimuPlus Flexible Annuloplasty Ring, SimuPlus Flexible Annuloplasty Band, SimuForm Semi-Rigid Annuloplasty Ring
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: May 29, 2020
Received: June 1, 2020

Dear Lisa Corbin:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201449

Device Name
SimuPlus™ Flexible Annuloplasty Ring
SimuPlus™ Flexible Annuloplasty Band
SimuForm™ Semi-Rigid Annuloplasty Ring

Indications for Use *(Describe)*
The SimuPlus flexible annuloplasty ring and band are indicated for use in patients undergoing surgery for diseased or damaged mitral valves. The band is indicated for the same use for tricuspid valves. The SimuPlus flexible annuloplasty ring and band provide support for the mitral annulus or tricuspid annulus (band only) and restrict expansion of the annulus.

The SimuForm semi-rigid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged mitral valves. The SimuForm semi-rigid annuloplasty ring provides support for the mitral annulus and restricts expansion of the 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.

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1.0 510(k) Summary

1.1 Applicant Information

Date Prepared: May 29, 2020

Applicant: Medtronic, Inc.
Medtronic Heart Valves Division
1851 E. Deere Ave.
Santa Ana, CA 92705

Contact Person: Lisa Corbin
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1.2 Device Name and Classification

Table 1-1: Device Name and Classification for Rebranded Simulus Devices

Trade Name	Predicate Device	Common Name	Classification Name	Regulation Number	Product Classification	Product Code	Classification Panel	Special Controls
SimuPlus™ Flexible Annuloplasty Ring, Model 7700FR	Simulus™ Flexible Annuloplasty Ring, Model 700FF (K052565)	Annuloplasty Ring	Ring, Annuloplasty	21 CFR 870.3800	Class II	KRH	Cardiovascular Devices Panel	Yes
SimuPlus™ Flexible Annuloplasty Band, Model 7700FB	Simulus™ Flexible Annuloplasty Band, Model 700FC (K052899)							
SimuForm™ Semi-Rigid Annuloplasty Ring, Model 7800RR	Simulus™ Semi-Rigid Annuloplasty Ring, Model 800SR (K072655)							

1.3 Design and Manufacturing Facility Addresses

Design Site: Medtronic Heart Valves Division
1851 E. Deere Ave.
Santa Ana, CA 92705
Establishment Registration Number: 2025587

Manufacturing Site: Medtronic Mexico S. de R.L. de CV
Av. Paseo Cucapah 10510 El Lago
Tijuana, Baja California Mexico C.P. 22210
Establishment Registration Number: 9617601

1.4 Device Description

1.4.1 SimuPlus Flexible Annuloplasty Ring and Band

The SimuPlus flexible annuloplasty ring (Model 7700FR) and band (Model 7700FB) consist of a flexible braided polyester fabric with a 3 mm cross-section. The ring or band may be implanted in the mitral annulus to stabilize the annulus following valve repair. The band may be implanted in the tricuspid annulus to stabilize the annulus following valve repair. The ring and band are marked at three points by colored sutures. Two markers correspond to the trigones (mitral valve) or septal commissures (tricuspid valve), and a central marker identifies the centerline of the ring or band. The individual ring or band size (26 mm to 42 mm in 2 mm increments) refers to the circumference between the green trigone markers on the ring or band. Silicone markers, impregnated with barium sulfate and tungsten, enable radiographic visualization. The ring and band are mounted to a holder to ease positioning and implantation.

The SimuPlus annuloplasty ring and band holder incorporates a chordal reference line to assist the surgeon during chordal repair procedures. A laterally stretched suture is present across the holder opening above the typical area of leaflet coaptation. This suture helps approximate the level of the annular plane. If the surgeon decides to include artificial chords in the valve repair, the chordal reference line may be useful when determining the level at which to tie the artificial chord knots. The chordal reference line does not require any additional steps to remove. It is removed with the holder after the retention sutures are cut.

1.4.2 SimuForm Semi-Rigid Annuloplasty Ring

The SimuForm semi-rigid annuloplasty ring (Model 7800RR) consists of a MP35N wire stiffener in the posterior segment, running from trigone to trigone. The ring stiffener is enclosed within a close-coiled MP35N spring that passes around the circumference of the annuloplasty ring. The spring is covered by a thin silicone sheath. Braided polyester fabric is used to cover and form the body of the ring. The ring has two green markers to indicate the anterior and posterior trigones. A green demarcation suture runs around the upper face of the ring. The individual ring size (24 mm to 40 mm in 2 mm increments) refers to the inner circumference between the green trigone markers on the ring. The internal spring and stiffener provide radiographic visualization around the circumference of the ring.

The SimuForm annuloplasty ring holder incorporates a chordal reference line to assist the surgeon during chordal repair procedures. A laterally stretched suture is present across the ring

holder opening above the approximate area of leaflet coaptation. This suture helps approximate the level of the annular plane. If the surgeon decides to include artificial chords in the valve repair, the chordal reference line may be useful when determining the level at which to tie the artificial chords knots. The chordal reference line does not require any additional steps to remove. It is removed with the holder after the retention sutures are cut.

1.5 Indications for Use

Table 1-2: Indications for Use for SimuPlus, SimuForm Rings and Bands

Device Name	Indications for Use
SimuPlus Flexible Annuloplasty Ring, Model 7700FR	The SimuPlus flexible annuloplasty ring and band are indicated for use in patients undergoing surgery for diseased or damaged mitral valves. The band is indicated for the same use for tricuspid valves. The SimuPlus flexible annuloplasty ring and band provide support for the mitral annulus or tricuspid annulus (band only) and restrict expansion of the annulus.
SimuPlus Flexible Annuloplasty Band, Model 7700FB	
SimuForm Semi-Rigid Annuloplasty Ring, Model 7800RR	The SimuForm semi-rigid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged mitral valves. The SimuForm semi-rigid annuloplasty ring provides support for the mitral annulus and restricts expansion of the annulus.

1.6 Comparison to Predicate Devices

1.6.1 SimuPlus Flexible Annuloplasty Ring and Band

The following characteristics of the SimuPlus flexible annuloplasty ring and band are identical to the Simulus flexible annuloplasty ring and band: implantable ring/band, intended use, principles of operation, sterilization, shelf life, and packaging. The SimuPlus flexible annuloplasty ring and band are substantially equivalent to the Simulus flexible annuloplasty ring and band as summarized in Table 1-3.

Table 1-3: Flexible Ring and Band Substantial Equivalence Comparison

Characteristic	SimuPlus Flexible Annuloplasty Ring and Band (Subject)	Simulus Flexible Annuloplasty Ring and Band (Predicate)	Equivalence
Indications for Use	The SimuPlus flexible annuloplasty ring and band are indicated for use in patients undergoing surgery for diseased or damaged mitral valves. The band is indicated for the same use for tricuspid valves. The SimuPlus flexible annuloplasty ring and band provide support for the mitral annulus or tricuspid annulus (band only) and restrict expansion of the annulus.	The ATS SIMULUS Annuloplasty Rings are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings provide support for the mitral or tricuspid annulus and restrict expansion of the annulus.	Substantially Equivalent

Table 1-3: Flexible Ring and Band Substantial Equivalence Comparison

Characteristic	SimuPlus Flexible Annuloplasty Ring and Band (Subject)	Simulus Flexible Annuloplasty Ring and Band (Predicate)	Equivalence
		The ATS SIMULUS FC Annuloplasty Bands are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty bands provide support for the mitral or tricuspid annulus and restrict expansion of the annulus	
Labeled Size Range*	26 mm, 28 mm, 30 mm, 32 mm, 34 mm, 36 mm, 38 mm, 40 mm, 42 mm	23 mm, 25 mm, 27 mm, 29 mm, 31 mm, 33 mm, 35 mm, 37 mm, 39 mm	Substantially Equivalent
Product Labeling	• Update to product name, indications, labeled size range • Update handle compatibility to Model 7686 annuloplasty handle • Update to 29-language eIFU, 6-language paper IFU	• Compatible with Model 752 annuloplasty handle • 16-language eIFU, 16-language paper IFU	Substantially Equivalent
*Note that there is no change to the construction or dimensions of the implantable ring/band. Modifications to the labeled size range reflect dimensional changes to the sizer accessory to align with standard industry sizing.			

1.6.2 SimuForm Semi-Rigid Annuloplasty Ring

The following characteristics of the SimuForm semi-rigid annuloplasty ring are identical to the Simulus semi-rigid ring: implantable ring, intended use, principles of operation, size range, sterilization, shelf life, and packaging. The SimuForm semi-rigid ring is substantially equivalent to the Simulus semi-rigid ring as summarized in Table 1-4.

Table 1-4: Semi-rigid Ring Substantial Equivalence Comparison

Characteristic	SimuForm Semi-rigid Annuloplasty Ring (Subject)	Simulus Semi-rigid Annuloplasty Ring (Predicate)	Equivalence
Indications for Use	The SimuForm semi-rigid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged mitral valves. The SimuForm semi-rigid	The ATS SIMULUS™ Semi-Rigid Mitral Annuloplasty Rings are for use in those patients undergoing surgery of diseased or damaged mitral valves in whom	Substantially Equivalent

Characteristic	SimuForm Semi-rigid Annuloplasty Ring (Subject)	Simulus Semi-rigid Annuloplasty Ring (Predicate)	Equivalence
	annuloplasty ring provides support for the mitral annulus and restricts expansion of the annulus.	the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings provide support for the natural annulus and restrict expansion of the annulus.	
Product Labeling	• Update to product name • Update handle compatibility to Model 7686 annuloplasty handle • Update to include 29-language eIFU, 6-language paper IFU	• Compatible with Model 752 annuloplasty handle • 16-language eIFU, 16-language paper IFU	Substantially Equivalent

1.7 Summary of Performance Data

Performance testing was not required to support labeling changes made to align with standard industry sizing.

1.8 Conclusion

The modifications to the Simulus devices do not impact the intended use or alter the fundamental scientific technology of the devices. There is no change to the implantable rings and bands. The SimuPlus and SimuForm rings and bands are therefore substantially equivalent to the currently marketed predicate devices.