1.0 510(k) Summary

1.1 Applicant Information

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Applicant:
Medtronic
Medtronic Heart Valves Division
1851 East Deere Ave
Santa Ana, CA 92705

Contact Person:
Tracy Gray
Regulatory Affairs
Medtronic
Phone: (949) 399-1678
Email: tracy.l.gray@medtronic.com

Alternate Contact
Zach Larsen
Regulatory Affairs Specialist
Medtronic
Phone: (949) 382-1034
Email: zach.s.larsen@medtronic.com

1.2 Device Name and Classification

Trade Name:	Tri-Ad™ 2.0 Adams tricuspid band
Common Name:	Tri-Ad 2.0 Adams
Classification Name:	Annuloplasty Ring
Predicate Device:	Tri-Ad™ Semi-Flexible Tricuspid Annuloplasty Ring (K093903)
Regulation Number:	21 CFR 870.3800
Product Classification:	Class II
Product Code:	KRH
Classification Panel:	Cardiovascular Devices Panel
Special Controls:	Yes

1.3 Address of Manufacturing Facilities

Design Site:
Medtronic Heart Valves Division
1851 E Deere Ave

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

The Tri-Ad 2.0 Adams, Model 900SFC, consists of an MP35N polished and formed wire stiffener fitted with 2 end caps. The band is covered with a braided polyester fabric. The stiffener runs from the posteroseptal commissure to the anterior segment distal to the anteroposterior commissure. The stiffener helps remodel and stabilize the enlarged portion of the tricuspid annulus. The band has 3 radial green markers to locate the following 3 areas of the band:

- The end of the stiffener section at the posteroseptal commissure.
- The anteroposterior commissure.
- The end of the stiffener section in the anterior segment of the band.

A green demarcation suture runs around the middle of the band in the stiffener region. The band size refers to the dimension of the band where the implantation sutures are placed, except in the stiffener region. The internal stiffener, and the radiopaque core in both fully flexible ends of the band, provide radiographic visualization along the entire circumference of the band. The band is available in the following sizes: 26 mm, 28 mm, 30 mm, 32 mm, 34 mm, and 36 mm.

1.5 Indications for use

The Tri-Ad 2.0 Adams tricuspid band is indicated for the reconstruction or remodeling of pathological tricuspid valves. The band provides support and restricts expansion of the tricuspid annulus.

1.6 Comparison to Predicate Devices

The Tri-Ad 2.0 Adams tricuspid band is identical to the Tri-Ad Semi-Flexible Tricuspid Annuloplasty Ring in the following characteristics: Intended Use, Principles of Operation, Sterilization, Shelf Life, Packaging and Size Range. The Tri-Ad 2.0 Adams tricuspid band is substantially equivalent to the Tri-Ad Semi-Flexible Tricuspid Annuloplasty Ring according to the comparison table below.

Characteristic	**Tri-Ad 2.0 Adams tricuspid band (Subject)**	**Tri-Ad Semi-Flexible Tricuspid Annuloplasty Ring (Predicate)**	**Equivalency**
Indications for Use	The Tri-Ad 2.0 Adams tricuspid band is indicated for the reconstruction or remodeling of pathological tricuspid valves. The band provides support and restricts expansion of the tricuspid annulus.	The Tri-Ad Semi-Flexible Tricuspid Annuloplasty Ring is indicated for use in patients undergoing surgery for diseased or damaged tricuspid valves. The Tri-Ad Semi-Flexible Tricuspid Annuloplasty Ring provides support for and restricts expansion of the tricuspid annulus.	Substantially Equivalent
Product Labeling	Minor modifications including: • Update to product name • Addition of new handle		Substantially Equivalent

1.7 Summary of Performance Data

Verification testing was used to verify the performance characteristics of the Tri-Ad™ 2.0 Adams tricuspid band. The following studies were performed:

- Visual Inspection
- Biocompatibility
- Sterilization
- Design Validation / Human Factors Engineering

1.8 Conclusion

Based upon the testing performed, the modifications to the Tri-Ad 2.0 Adams do not affect the intended use of the devices or alter the fundamental scientific technology of the devices. No change has been made to the implantable band. Therefore, Tri-Ad 2.0 Adams is substantially equivalent to the currently marketed predicate device.