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**510(k) Summary**

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**I. Applicant Information**

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**II. Device Information**

**Name of Device:** AtriClip® LAA Exclusion System

**Common Name:** Implantable Clip and Clip Applier

**Classification Name:** Implantable Clip and Clip Applier (21 CFR 878.4300)  
Class II  
Product Code: PZX  
Classification Panel: General and Plastic Surgery

**Predicate Device:** The device proposed for modification in this submission is the AtriClip LAA Exclusion System cleared via K181474 on June 28, 2018.

The following reference devices were also used in this submission:

- |           |                               |           |                               |
|-----------|-------------------------------|-----------|-------------------------------|
| • K093679 | AtriClip LAA Exclusion System | • K153500 | AtriClip LAA Exclusion System |
| • K122276 | AtriClip LAA Exclusion System | • K163261 | AtriClip LAA Exclusion System |
| • K131107 | AtriClip LAA Exclusion System | • K172742 | AtriClip LAA Exclusion System |
| • K142120 | AtriClip LAA Exclusion System | • K173031 | AtriClip LAA Exclusion System |
| • K150996 | AtriClip LAA Exclusion System | • K180010 | AtriClip LAA Exclusion System |
| • K160454 | AtriClip LAA Exclusion System | • K181474 | AtriClip LAA Exclusion System |

### III. Device Description

The AtriClip Exclusion System contains a clip for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005, 2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies. The Clip is pre-loaded on a disposable Clip applicator. The AtriClip Exclusion System does not contain natural rubber latex components.

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### IV. Indications For Use

The AtriClip LAA Exclusion System is indicated for the exclusion of the left atrial appendage, under direct visualization, in conjunction with other cardiac surgical procedures.

Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or any other viewing technologies.

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### V. Comparison of Technological Characteristics with the Predicate Device

AtriCure updated the LAA Exclusion System indications and device description in the instructions for use labeling. A comparison of the technological characteristics with the predicate device are provided in **Table 1** below.

**Table 1: Comparison of Technological Characteristics**

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
Proprietary Name	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip  AtriClip® LAA Exclusion System with preloaded V-Clip	AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip  AtriClip® LAA Exclusion System with preloaded V-Clip	n/a
Model Numbers	LAA035 LAA040 LAA045 LAA050 ACH135 ACH140 ACH145 ACH150 ACH235 ACH240 ACH245 ACH250 PRO135 PRO140 PRO145 PRO150 PRO235 PRO240 PRO245 PRO250  ACHV35 ACH40 ACHV45 ACHV50 PROV35 PROV40 PROV45 PROV50	LAA035 LAA040 LAA045 LAA050 ACH135 ACH140 ACH145 ACH150 ACH235 ACH240 ACH245 ACH250 PRO135 PRO140 PRO145 PRO150 PRO235 PRO240 PRO245 PRO250  ACHV35 ACH40 ACHV45 ACHV50 PROV35 PROV40 PROV45 PROV50	n/a
Indications for Use	The AtriClip LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage, performed	The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, performed under direct	Similar. AtriClip devices have

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
	<p>under direct visualization and in conjunction with other cardiac surgical procedures.</p> <p>Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.</p>	<p>visualization and in conjunction with other cardiac surgical procedures.</p> <p>Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or other appropriate viewing technologies.</p>	the same intended use
Device Description in the Instructions for Use	The AtriClip LAA Exclusion System contains the Gillinov-Cosgrove LAA Clip (Clip) for occlusion of the heart's left atrial appendage (LAA). The Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip does not contain natural rubber latex component.	<p>The AtriClip LAA Exclusion System contains {*Clip Type} LAA Clip (Clip) for exclusion of the heart's left atrial appendage (LAA). Preclinical animal studies (Kamohara 2005, 2006) demonstrate that complete exclusion with the Clip also results in acute and chronic electrical isolation of the LAA. A human clinical study (Starck 2012) has demonstrated acute electrical isolation. Chronic electrical isolation has not been evaluated in human clinical studies.</p> <p>The Clip is pre-loaded on a disposable Clip applier. The AtriClip LAA Exclusion System with preloaded {*Clip Type} Clip does not contain natural rubber latex component.</p> <p>* AOD1: "Gillinov-Cosgrove" * AOD2: "V"</p>	Different.  AtriClip devices have the same intended use
Preloaded Clip	<p><b>AOD1:</b> Preloaded Gillinov-Cosgrove Clip</p> <p><b>AOD2:</b> Preloaded V-Clip</p>	<p><b>AOD1:</b> Preloaded Gillinov-Cosgrove Clip</p> <p><b>AOD2:</b> Preloaded V-Clip</p>	Same
Shelf Life	3 years	3 years	Same
Biocompatibility	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices	Passed. Materials have been assessed based on ISO 10993 and are commonly employed in tissue contacting devices	Same
Sterilization	Gamma Irradiation.	Gamma Irradiation.	Same

Feature	Predicate (K181474) AtriClip™ LAA Exclusion System	Subject AtriClip™ LAA Exclusion System	Equivalence Comparison
Sterility Assurance Level	10 <sup>-6</sup> SAL	10 <sup>-6</sup> SAL	Same

The proposed changes in the indications for use statement and instruction for use were supported by published animal and clinical data. The proposed changes do not include any change to intended use, contraindications, or precautions. Additional warnings have been added to the labeling:

Warning:

- The safety and effectiveness of this device in atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.
- AtriClip placement that allows blood flow into the LAA may not result in complete exclusion and/or electrical isolation.

The proposed changes have no impact on design, operating principles, performance specifications, packaging, sterilization or expiring dating.

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## VI. Performance Data

The proposed changes do not include any change to design or performance specifications of the AtriClip LAA Exclusion System. Additionally, the proposed changes did not modify the intended use, therefore the previously submitted bench and animal data remain valid for the AtriClip LAA Exclusion System.

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## VII. Conclusions

A review of the risk analysis concluded there is no overall change to the risk profile of the proposed AtriClip LAA Exclusion System versus the previously cleared AtriClip LAA Exclusion System as the modifications to the proposed AtriClip LAA Exclusion System IFU do not add or remove any features of the device or change the clinical application. AtriCure has demonstrated that the AtriClip LAA Exclusion System IFU, as labeled per the proposed Indication for Use and IFU description section, is substantially equivalent to the predicate LAA Exclusion System (K181474) as there is no change to intended use, operating principals, or function of the device.