K 122276

AtriCure®

510(k) Summary

AUG 29 2012

General Information

Classification	Class 2
Trade name	AtriClip LAA Exclusion System with preloaded Gillinov-Cosgrove Clip
Common name	Implantable Clip
Classification Name	Clip, Implantable (21 CFR 878.4300, Product Code FZP)
Manufacturer	AtriCure, Inc. 6217 Centre Park Dr. West Chester, OH 45069 P: 513-755-4100 F: 513-755-4108
Contact	James Lucky, RAC Vice President Quality Systems and Regulatory Affairs
Date of Submission	July 24, 2012

Intended Use

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

Cleared Device

The device proposed for modification in this submission is the AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip cleared via 510(k) K093679 on June 10, 2010.

Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier. When closed, the Clip applies uniform pressure over the length of the Clip to ensure consistent, reproducible, and secure occlusion of the left atrial appendage (LAA). The Clip is available in the following lengths to accommodate different sizes of LAA: 35 mm, 40 mm, 45 mm, and 50 mm. This Special 510(k) does not include any changes to the Clip.

The Clip Applier is a disposable device with a handle, shaft, and an end effector which contains the Clip. This Special 510(k) includes modifications to the Clip Applier including both lateral and vertical articulation of the end effector and deployment via pulling a deployment tab at the proximal end of the handle.

Materials

All materials in the modified Clip Applier are suitable for their intended use. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

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Testing

The modified Clip Applier was tested on the cadaver model to confirm the modifications do not affect the ability to successfully deploy the Clip on the left atrial appendage. Additional testing per 21 CFR 820.30 and AtriCure's Quality System was performed to verify the modified Clip Applier's conformance to design controls and specification. Testing determined that the modified Clip Applier was able to successfully deploy the Clip on the LAA and that the modified Clip Applier conformed to design controls and product specifications.

Summary of Equivalence

The modified AtriClip LAA Exclusion System is equivalent to the previously cleared AtriClip LAA Exclusion System as there is no change to indications for use/intended use, the implant Gillinov-Cosgrove Clip, or the basic design of the Clip Applier. The modifications to the Clip Applier do not affect the ability of the Clip to be successfully deployment on the LAA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 29 2012

AtriCure
James Lucky, RAC
Vice President of Quality Systems and Regulatory Affairs
6217 Centre Park Drive
West Chester, OH 45069

Re: K122276
Trade/Device Name: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove™ Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: July 24, 2012
Received: July 31, 2012

Dear Mr. Lucky:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known) K122276

Device Name: AtriClip LAA Exclusion System with Preloaded Gillinov-Cosgrove Clip

Indications for Use:

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

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122276