AtriCure®

K131107

510(k) Summary

MAY 14 2013

General Information

Classification	Class 2
Trade name	AtriClip™ Gillinov-Cosgrove™ LAA 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	Rebecca Walters, RAC Regulatory Affairs Manager
Date of Submission	April 17, 2013

Intended Use

The AtriClip Gillinov-Cosgrove LAA Clip 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 and K122276 on August 29, 2012.

Device Description

The AtriClip Gillinov Cosgrove LAA Clip is a single use, sterile, self-closing, implantable Clip to be deployed with a Reusable 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.

This Special 510(k) includes modifications to package the Clip individually to be loaded on a Reusable Clip Applier.

Materials

There are no changes to materials of the Clip. All materials in the Clip are suitable for their intended use. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

The Clip was tested to confirm new packaging of the Clip adequately protects the device during shipment. Complete Design Control testing for the Clip was previously included in the original 510(k) K093679.

Summary of Equivalence

The AtriClip Gillinov-Cosgrove LAA Clip 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 and Clip Applier configuration. The modifications 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 Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2013

AtriCure, Inc.
Rebecca Walters
Regulatory Affairs Manager
6217 Centre Park Drive
West Chester, OH 45069

Re: K131107
Trade/Device Name: AtriClip™ Gillinov-Cosgrove™ LAA Clip
Regulation Number: 21 CFR 870.4300
Regulation Name: Clip, Implantable
Regulatory Class: Class II
Product Code: FZP
Dated: April 17, 2013
Received: April 19, 2013

Dear Ms. Walters:

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 contact 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. 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,

Matthew G. Hillebrenner

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

Enclosure

Indications for Use

510(k) Number (if known) K131107

Device Name: AtriClip Gillinov-Cosgrove LAA Clip

Indications for Use:

The AtriClip Gillinov-Cosgrove Clip 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 (Part 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Matthew G. Hillebrenner