AtriCure®

K093679

510(k) Summary

JUN 10 2010

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 Assurance and Regulatory Affairs
Date of Submission	November 27, 2009

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.

Predicate Devices

The predicate devices for the AtriClip LAA Exclusion System are the Weck Hem-O-Lok® Ligating Clip and Clip Applier (K030311), Medtronic VNUS U-Clip and Applier (K031623), Tyco AutoSuture TA and GIA Staplers (K032696), Power Medical SurgASSIST® Straight Linear 4 Row No Knife DLUs with Reloads (K040398), Demetech Braided Nonabsorbable Polyester Suture and needle driver (K023030) and Gore SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material (K043056).

Device Description

The AtriClip LAA Exclusion System consists of a single use, sterile, self-closing, implantable Clip preloaded on a Single Use Clip Applier, and a Selection Guide to aid in appropriate Clip size selection. The frame assembly of the implantable Clip consists of two springs connecting two opposing tubes which are covered with pressure pads. This assembly is covered with a knit fabric. 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.

The Clip Applier is a disposable device with a handle, shaft, and an end effector which contains the Clip. Both sides of the Clip are free to move within the end effector when activated. Pulling the thumb lever proximally opens the Clip. The bias of the springs in the Clip allows both the clip and the lever to return to the closed position when the lever is released.

Materials

All materials in the AtriClip LAA Exclusion System are suitable for their intended use and have been used in previously cleared products. Testing was conducted in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Predicate Comparison

The technological characteristics of the device are the same as the predicate devices. The same materials are used in the AtriClip and predicate devices. The sizes of the devices are equivalent and are provided in similar ranges. The method of LAA closure, permanent approximation of the sides of the LAA, is the same for the AtriClip and the predicates. All of the devices may be repositioned on the LAA prior to deployment and once deployed exert similar pressures on the tissue.

Non-Clinical Testing

The AtriClip was tested on in both acute and chronic models ranging from 7 days to 90 days duration. Testing presented in the 510(k) document demonstrated complete appendage exclusion both acutely and long-term in all animals with no adverse events attributed to the Clip device. Post-implant verification of efficacy confirmed there was no communication between the LAA and left atrium in all animals.

Clinical Testing

The AtriClip has been evaluated for safety and efficacy in a controlled clinical study of seventy subjects. The results of the study demonstrate the excellent performance of the product in its ability to exclude the LAA in a safe and efficient manner. Efficacy has been demonstrated at a very high rate intra-procedurally and this rate has been shown to improve as further healing was achieved. The observed exclusion rate of 95.1% composite (both intra-operative and 3 month) and 98% at 3 month follow-up support that this procedure can achieve excellent efficacy results.

The safety of the device and procedure has been well established through a careful scrutiny of all events reported in the study. Independent physician adjudication has demonstrated that there were no events that were in any way linked to the device or the procedure. The primary safety endpoint event rate in this trial is 0%. These results confirm the safety of the product and the procedure. The results further support the technical and clinical comparability of the product to other currently marketed options for LAA exclusion and therefore provides the clinical support to demonstrate a substantial equivalence of the AtriClip to the identified predicate devices.

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Summary of Substantial Equivalence

As demonstrated by the predicate comparison of technological characteristics, data provided in the non-clinical studies and clinical testing, the AtriClip LAA Exclusion System is equivalent to the predicate products. The data presented in K093679 demonstrate that the device is as safe, as effective and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 10 2010

AtriCure, Inc.
c/o Mr. James Lucky
Vice President of Quality Assurance and Regulatory Affairs
6217 Centre Park Drive
West Chester, OH 45069

Re: K093679
AtriClip™ LAA Exclusion System w/Pre-loaded Gillnov-Cosgrove™ Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: FZP
Dated: June 1, 2010
Received: June 2, 2010

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.

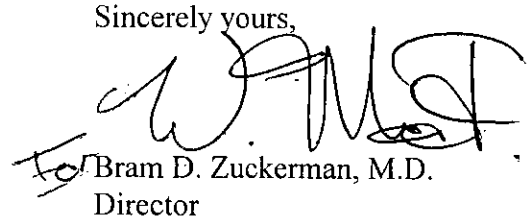
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Enclosure

STATEMENT: INDICATION FOR USE

510 (k) Number: K093679

Device Name: AtriClip LAA Exclusion System

Indications for 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.

Prescription Use ___X__ Over the Counter Use _____
(Part 21 CFR 801 Subpart D) and/or (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093679