K111020

JUN - 9 2011

ATRICURE DISSECTOR™ 510(k) SUMMARY

General Information

Date Compiled	April 11, 2011
Classification	Class II (Surgical Lamp) 21 CFR 878.4580
Product Code	FTD, GDI
Trade Name	AtriCure *Dissector*™
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069
Contact	James L. Lucky VP of Quality Assurance and Regulatory Affairs (513) 755-5754

Indications for Use

The AtriCure *Dissector*™ is intended to dissect soft tissue during general, ENT, thoracic, urological and gynecological surgical procedures. The Dissector's battery-powered light source is used to navigate soft tissue for identification of anatomic structures.

Cleared Device

The device proposed for modification in this submission is the AtriCure *Dissector*™ (K041681).

Device Description

The AtriCure *Dissector*™ is a hand held, single use, surgical articulated dissector with integral light source intended to for use by qualified surgeons only. The surgeon is able to articulate the distal member of the device by means of hand actuated rotation knob. The surgeon directly controls the amount of articulation and tissue dissection. A small light source is attached to the distal tip of the articulation member, which remains illuminated for a minimum of four (4) hours. Multiple models of the *Dissector*™ are available with varying shaft lengths to accommodate surgeon preference and differing patient habitus.

Materials

All materials used in the manufacture of the AtriCure *Dissector*™ are suitable for their intended use and have been used in numerous previously cleared products. Materials used include, but are not limited to, medical grade silicone, stainless steel, medical grade adhesive, and acrylic epoxy resin. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted according to the Design Control requirements as defined in 21 CFR 820.30 to evaluate conformance to product specification and substantial equivalence to the legally marketed device. These activities included Risk

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Analysis, Process Verification, and Biocompatibility Testing. Biocompatibility testing was conducted according to ISO 10993-1 to confirm that the modified *Dissector*™ is safe for limited use (<24 hrs) as a patient contacting device.

Summary of Substantial Equivalence

The modified AtriCure *Dissector*™ (MID1/GPD1) proposed in this submission is considered substantially equivalent to the *Dissector*™ (MID1) device cleared via K041681. The modification does not affect the technological characteristics, scientific principles, or performance specifications. The indications for use, basic overall function, and materials used are substantially equivalent.

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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

JUN - 9 2011

AtriCure, Inc.
% Mr. James L. Lucky
VP, Quality Assurance and Regulatory Affairs
6217 Centre Park Drive
West Chester, Ohio 45069

Re: K111020
Trade/Device Name: AtriCure Dissector™
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTD, GDI
Dated: May 19, 2011
Received: May 23, 2011

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111020

Device Name: AtriCure *Dissector*™

Indications For Use:

The AtriCure *Dissector*™ is intended to dissect soft tissue during general, ENT, thoracic, urological and gynecological surgical procedures. The Dissector's battery-powered light source is used to navigate soft tissue for identification of anatomic structures.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R.P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111020