

510(k) Summary

General Information

JUL 01 2004

Classification	Class I/II
Trade Name	AtriCure <i>dissector</i> TM
Manufacturer	AtriCure, Inc. 6033 Schumacher Park Drive West Chester, OH 45069
Contact	Elsa Abruzzo Vice President, Regulatory and Clinical Affairs

Intended Use

The AtriCure *dissector*TM 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.

Predicate Devices

The predicate device for the AtriCure *dissector*TM is the Stryker Knifelight Lighted Knife (K961122). The Stryker Knifelight Lighted Knife is classified as a Dissector, Surgical, General and Plastic Surgery, per 21CFR878.4800 and a Lamp, Surgical, per 21CFR 878.4580.

Device Description

The AtriCure *dissector*TM is a hand held, single use, surgical articulated *dissector* with integral light source.

Materials

All materials used in the manufacture of the AtriCure *dissector*TM are suitable for this use and have been used in numerous previously cleared products. Testing was conducted in Accordance with ISO 10993-1 to ensure appropriate biocompatibility of all materials.

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The AtriCure *dissector*[™] is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AtriCure, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

JUL 01 2004

Re: K041681
Trade/Device Name: AtriCure Dissector™
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTD
Dated: June 17, 2004
Received: June 21, 2004

Dear Mr. Job:

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 such 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); 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.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041681

Device Name: AtriCure *dissector*™

Indications For Use:

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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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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