MAY 21 2001

K003446S1

510(k) Summary

Aortic Connector System

Common/Classification Name: Implantable Clip and delivery system as classified under 21 CFR 878.4300 and 4800

St. Jude Medical
Anastomotic Technology Group
6500 Wedgwood Rd.
Maple Grove, MN 55311

Telephone: (763) 383-2559
Fax: (763) 383-2771
Contact: Milana Solganik, Director of Regulatory Affairs

Prepared: November 1, 2000

A. Legally Marketed Predicate Devices

The Aortic Connector System is substantially equivalent to the U.S. Surgical AutoSuture Vascular Anastomosis Clip Cartridge and Applier (K970793).

B. Device Description

The Aortic Connector System is a mechanical device used to facilitate an aortic vein graft anastomosis. The connector replaces sutures to create a secure, patent, and reproducible anastomosis. The Symmetry Aortic Connector System consists of a self expanding implantable connector and delivery system.

C. Indications for Use

The Aortic Connector System is intended to create the aortic anastomosis of aortic autologous vein grafts.

D. Substantial Equivalence Summary

Both devices are intended to be used in creating vascular anastomoses. The St. Jude Medical Anastomotic Technology Group Mechanical Anastomosis Connector is made of a Nickel Titanium alloy (Nitinol) in a "U" shape with rounded ends. The U.S. Surgical clip is made of Titanium in a "C" shape with blunted ends. The ends of both clips pinch the edges of the vessels together without penetrating the vessel wall.

The primary difference between the devices is the delivery method. The U.S. Surgical applier fires the clips one at a time, and the applier must be manually moved circumferentially around the anastomosis site. The St. Jude Medical Anastomotic

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Technology Group Mechanical Anastomosis Connector is a unitary device with all clipping elements being deployed simultaneously around the circumference.

E. Technological Characteristics

See **Device Description** above.

F. Testing

Mechanical, In Vitro, and animal, testing has been conducted which demonstrates that the performance of the Aortic Connector System is equivalent to standard suture anastomoses.

G. Conclusion

St. Jude Medical has demonstrated through its comparison of performance with standard suture anastomoses that the Aortic Connector System is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. Al Flory
Vice President, Clinical
and Regulatory Affairs
St. Jude Medical
Cardiac Surgery Division
Anastomotic Technology Group
6500 Wedgwood Road
Maple Grove, Minnesota 55311

Re: K003446
Trade/Device Name: Symmetry Aortic Clip System
Regulation Number: 878.4300
Regulatory Class: II
Product Code: FZP
Dated: February 16, 2001
Received: February 20, 2001

Dear Mr. Sheridan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Mark N Melkerson

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

K003446

510(k) Number (if known): K003446

Device: Mechanical Anastomosis System

Indications for Use:

The Aortic Connector System is intended to create the aortic anastomosis of aortic autologous vein grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003446