

K060902

**APPENDIX A: 510(k) SUMMARY**

Sponsor/Submitter: Abbott Laboratories  
Abbott Vascular Inc.  
400 Saginaw Drive  
Redwood City, CA 94063

JUL - 7 2006

Contact Person: Daun Putnam  
Regulatory Affairs  
Phone: 650-474-3323  
Fax: 650-474-3041

Date of Submission: March 31, 2006

Device Trade Name: StarClose™ Introducer Set

Device Common Name: Introducer Set

Device Classification: Class II

Regulation Number: 21 CFR 870.1340

Classification Name: Catheter Introducer

Product Code: DYB

Predicate Device: StarClose™ Introducer Set (K030723)

Intended Use: The StarClose™ Introducer Set is intended for use in procedures requiring percutaneous introduction of intravascular devices.

Device Description: The StarClose™ Introducer Set consists of a 6F Introducer, a Dilator and a "J"-tip guidewire and is for use in gaining access to blood vessels for diagnostic and interventional procedures.

Summary of Substantial Equivalence: The StarClose™ Introducer Set is substantially equivalent to the predicate device. Substantial equivalence was confirmed through non-clinical testing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL - 7 2006

Abbott Vascular, Inc.  
c/o Mr. Daun Putnam  
Coordinator, Regulatory Affairs  
400 Saginaw Drive  
Redwood City, CA 94063

Re: K060902  
Trade Name: StarClose™ Introducer Set  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: II (two)  
Product Code: DYB  
Dated: June 8, 2006  
Received: June 9, 2006

Dear Mr. Putnam:

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.

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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. 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
for Bram D. Zuckerman, M.D.

Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**APPENDIX B: INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K\_060902\_\_\_\_\_.

Device Name: StarClose™ Introducer Set

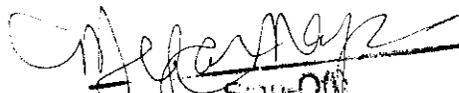
Indications for Use: The StarClose™ Introducer Set is intended for use in procedures requiring percutaneous introduction of intravascular devices.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division of Small-Off)  
Division of Cardiovascular Devices  
510(k) Number   K060902