K051125

APPENDIX A. 510(k) SUMMARY

Sponsor/Submitter:	Abbott Laboratories (Perclose, Inc.) Abbott Vascular Devices 400 Saginaw Drive Redwood City, CA 94063
Contact Person:	Kim Smith-Servance Regulatory Affairs Manager Phone:(650) 474-3383 Fax:(650) 474-3041
Date of Submission:	May 2, 2005
Device Trade Name:	StarClose™ Vascular Closure System
Device Common Name:	Vascular Closure System
Device Classification:	Class II
Regulation Number:	21 CFR 878.4300 21 CFR 870.1340
Classification Name:	General and Plastic Surgery Devices
Product Code:	FZP DYB
Predicate Device:	StarClose™ Vascular Closure System (K020879)
Intended Use:	The StarClose™ Vascular Closure System is intended for use for use to approximate vascular tissue for achieving hemostatic closure of puncture sites to aid healing in minimally invasive procedures under direct or endoscopic visualization
Device Description:	The StarClose™ Vascular Closure System is designed to deliver a nitinol clip to close vascular puncture sites to achieve hemostasis.
Summary of Substantial Equivalence:	The StarClose™ Vascular Closure System is substantially equivalent to the predicate device. Substantial equivalence was confirmed through non-clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Ms. Kim Smith-Servance
Manager, Regulatory Affairs
Abbott Laboratories (Perclose, Inc.)
Abbott Vascular Devices
400 Saginaw Drive
Redwood City, California 94063

Re: K051125
Trade/Device Name: StarClose™ Vascular Closure System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: May 2, 2005
Received: May 10, 2005

Dear Ms. Smith-Servance:

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.

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) 276-0115 . 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051125

APPENDIX B. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K_____

Device Name: StarClose™ Vascular Closure System

Indications For Use: The StarCloseTM Vascular Closure System is intended for use for use to approximate vascular tissue for achieving hemostatic closure of puncture sites to aid healing in minimally invasive procedures under direct or endoscopic visualization.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051125