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DEC 0 6 2001

510(K) SUMMARY

A. Sponsor/Submitter:

Perclose, an Abbott Laboratories Company
400 Saginaw Drive
Redwood City, CA 94063
Tel: (650) 474-3000
Fax: (650) 474-3020

B. Contact Person:

Patty Hevey
Clinical Affairs Coordinator
(650) 474-3202

C. Date of Submission: November 6, 2001

D. Trade (Brand) Name: Abbott Vascular Suture Anastomosis Device

E. Common Name: Suture Delivery Device

F. Classification: Class II

G. Classification Name: Suture, Implantable

H. Product Code: GAW

I. Predicate Devices:

1. U.S. Surgical Corporation VCS Anastomotic Clip Cartridge, K970793
2. Coalescent Surgical Sutured-Clip, K994160
3. Deknatel (Genzyme Corporation) Deklene® II Surgical Suture

J. Intended Use:

The Abbott Vascular Suture Anastomosis Device is intended for use in the delivery of 10 interrupted sutures to assist the surgeon in the creation of vascular anastomoses.

K. Device Description:

The Abbott Vascular Suture Anastomosis Device is a hand-held surgical device that simultaneously deploys 10 lengths of 7-0 polypropylene suture at the site of a vascular anastomosis via a hydraulic delivery mechanism. The Abbott Vascular Suture Anastomosis Device is available in two models for creating either side-to-side or end-to-side anastomoses. After deployment of

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the device, the surgeon completes the anastomosis by hand-tying the appropriate surgical knots. Optional accessories available for use with the Abbott Vascular Suture Anastomosis (AVSA) Device include the Heartflo™ Scissors and the Heartflo™ Handle.

The Abbott Vascular Suture Anastomosis Device is a prescription device, restricted to use by physicians trained in vascular surgery.

The Abbott Vascular Suture Anastomosis Device is EtO sterilized and non-pyrogenic in an unopened undamaged package, for single use only.

F. Summary of Substantial Equivalence:

Perclose has submitted information on design, indications, materials, and principle of operation to establish that the Abbott Vascular Suture Anastomosis Device is substantially equivalent to currently marketed predicate devices.

The Abbott Vascular Suture Delivery Device has essentially the same intended use as the predicate devices. Questions regarding the effects of any new technological characteristics of the Abbott Vascular Suture Anastomosis Device have been answered through accepted scientific methods. These methods assessed the new characteristics with regard to functionality and reliability under simulated and actual conditions of use. Results of scientific testing have ensured that different materials are biocompatible and physical properties are appropriate for the intended use. Scientific tests conducted to ensure the safety and effectiveness of the Abbott Vascular Suture Anastomosis Device included:

- Dermal Sensitization
- Cytotoxicity
- Intracutaneous Reactivity
- Systemic Toxicity
- Hemolysis
- Attachment strength of critical components
- Functional bench testing (e.g., suture deployment, suture spacing, suture management, tissue capture)
- *In vivo* animal testing

In conclusion, the Abbott Vascular Suture Anastomosis Device has been shown to be substantially equivalent to the Class II predicates on which the device is based.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Perclose
Ms. Patty Hevey
Clinical Affairs Coordinator
400 Saginaw Drive
Redwood City, California 94063

Re: K013683
Trade Name: Abbott Vascular Suture Anastomosis Device
Regulation Number: 878.5010
Regulation Name: Polypropylene Suture
Regulatory Class: II
Product Code: GAW
Dated: November 14, 2001
Received: November 15, 2001

Dear Ms. Hevey:

We have reviewed your Section 510(k) premarket 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 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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walter, MD

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

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INDICATIONS FOR USE STATEMENT

510(k) Number:	K013683
Device Name:	Abbott Vascular Suture Anastomosis Device
Indications for Use:	The Abbott Vascular Suture Anastomosis Device is indicated for use in the delivery of 10 interrupted sutures to assist the surgeon in the creation of vascular anastomoses.

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

510(k) Number K013683