K991286

NOV 18 1999

Attachment F
510(k) Summary

Introduction:	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
1. Submitter's name address, contact	Avocet Medical, Inc. 100 Great Oaks Blvd. Suite A San Jose, CA 95119 (408) 574-7855 (phone) (408) 574-7865 (fax) Contact person: Judith Blunt Date prepared: April 13, 1999
2. Device name	Common or Usual Name: Prothrombin Time Test Classification Name: Prothrombin Time Test Trade or Proprietary Name: Avocet$_{PT\text{-}Home}$
3. Predicate device:	The Avocet$_{PT}$ System: device for testing Prothrombin Time and INR in whole blood.
4. Device description:	The Avocet$_{PT\text{-}Home}$ is a membrane-based, dry-reagent system for use with fresh capillary whole blood. The system uses a membrane to separate plasma from red cells. The membrane contains calcium and thromboplastin, and permits the reactions of the complete extrinsic pathway to occur with minimal distortion from membrane surface interactions. Thrombin generation is monitored optically using a rhodamine-110-based fluorescent thrombin substrate. Fluorescence kinetics are analyzed to produce a prothrombin-time-equivalent parameter that is converted to an international normalized ratio (INR) value. The Avocet$_{PT\text{-}Home}$ is the same device as the Avocet$_{PT}$, except that it has the citrated whole blood and plasma sample modes deactivated in the meter software, a test strip CAL code is only given for capillary whole blood and the labeling has been modified for readability by the lay user.

5. Intended use:	The Avocet$_{PT}$ is an *in vitro* diagnostic system that provides a quantitative prothrombin time result, expressed as an International Normalized Ratio (INR). The Avocet$_{PT\text{-}Home}$ is intended for quantitative prothrombin time testing of fresh, capillary whole blood for monitoring of oral anticoagulation therapy by trained patients or their caregivers, on the prescription or other order of a treating physician.
6. Comparison to predicate device	The Avocet$_{PT\text{-}Home}$ is substantially equivalent in materials, design and intended use to other products that measure Prothrombin Time INR in human blood. Most notably, it is substantially equivalent to the Avocet $_{PT}$, manufactured by Avocet Medical Incorporated. In fact, it is identical in materials, design and function to the Avocet$_{PT}$, but the labeling has been changed for physician directed, home use.
6. Summary of performance data	The Avocet$_{PT\text{-}Home}$ System was found to perform equivalently when used by trained lay users and healthcare professionals. Furthermore, both user populations generated results found to be equivalent to an established reference method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1999

Ms. Jill Falcone
Vice President of Regulatory Affairs and
Quality Assurance
AVOCET Medical Incorporated
100 Great Oaks Boulevard
San Jose, California 95119-1347

Re: K991286
Trade Name: Avocet AcuSure System
Regulatory Class: II
Product Code: GJS
Dated: October 22, 1999
Received: October 25, 1999

Dear Ms. Falcone:

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.

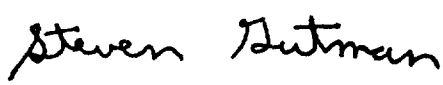
Under Section 522 (a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA, are required to conduct postmarket surveillance studies. The FDA believes that under Section 522 (a) (2), discretionary postmarket surveillance will be in order for the Avocet AcuSure System. Please contact Valerie Dada at (301) 594-1293 within 15 days of receipt of this letter, to arrange a meeting to discuss the objectives and design of a future discretionary postmarket surveillance study.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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"(21 CFR 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,



Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment G
Premarket Notification
Indications for Use Statement

Device Name: Avocet$_{PT\text{-}Home}$

Indications for Use:

The Avocet$_{PT\text{-}Home}$ is intended for quantitative prothrombin time testing of fresh, capillary whole blood for monitoring of oral anticoagulation therapy by trained patients or their caregivers, on the prescription or other order of a treating physician.

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991286

Prescription ✓