

FEB 3 2000

K994006

**Avocet Medical, Inc.
Premarket Notification, 510(k), for the Avocet AcuSure System (for Patient Self-Testing) and the AcuSure Pro System (for Professional Use)**

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.

Submitter name, address, contact, date prepared Avocet Medical, Inc.
100 Great Oaks Blvd.
San Jose, CA 95119
(408)-574-6638

Contact person: Jill Falcone

Date Prepared: November 22, 1999

Device Name Proprietary Name: Avocet AcuSure System (for Patient Self-Testing) and the Avocet AcuSure Pro System (for Professional Use)

Common Name: Prothrombin Time Test

Predicate Device The AcuSure System (for patient self-testing) and the AcuSure Pro System (for professional use) are exactly the same device except that the AcuSure System (for patient self-testing) has labeling and quality control recommendations for the home user whereas the AcuSure Pro System has labeling and quality control recommendations for the professional user. The quality control and performance characteristics sections of the labeling for the AcuSure Pro System contain the same language that was previously cleared for professional use in 510(k)# K980839.

Device Description The AcuSure and AcuSure Pro test strips and meter measure capillary blood PT levels. When the sample is applied to the target area on the test strip, the meter detects the electrical drop between two electrodes on the test strip and begins the test. Inside the membrane of the test strip the red blood cells are separated from the plasma. The membrane also contains the reagents necessary to cause the coagulation reaction (clot formation) to occur. The thrombin, formed as part of the coagulation reaction, reacts with a reagent, which causes a fluorescent molecule to be released. The

000337

time from the initial resistance drop to the onset of fluorescence is proportional to the prothrombin time of the sample.

Intended Use

The AcuSure System for Patient Self-Testing is intended for the quantitative prothrombin time testing of fresh, capillary whole blood by selected and suitably trained patients or their caregivers on the prescription of the treating physician. The AcuSure System for Patient Self-Testing is for the monitoring of patients on oral anticoagulant therapy and not intended to be used for screening purposes.

The AcuSure Pro System for Professional Use is intended for the quantitative prothrombin time testing of fresh, capillary whole blood by healthcare professionals. The AcuSure Pro System is for the monitoring of patients on oral anticoagulant therapy and not intended to be used for screening purposes.

**Comparison to
Predicate Device**

The AcuSure System (for patient self-testing) and the AcuSure Pro System (for professional use) are substantially equivalent. The AcuSure System (for patient self-testing) and the AcuSure Pro System (for professional use) are exactly the same device except that the AcuSure System (for patient self-testing) has labeling and quality control recommendations for the home user whereas the AcuSure Pro System has labeling and quality control recommendations for the professional user. The quality control and performance characteristics sections of the labeling for the AcuSure Pro System contain the same language that was previously cleared for professional use in 510(k)# K980839.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

FEB 3 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K994006
Trade Name: Avocet AcuSure System (for Patient Self-Testing) and the Avocet AcuSure Pro System (for Professional Use)
Regulatory Class: II
Product Code: GJS
Dated: November 11, 1999
Received: November 24, 1999

Dear Ms. Falcone:

We have reviewed your Section 510(k) notification of intent to market the Avocet AcuSure System (for Patient Self-Testing) and the Avocet AcuSure Pro System (for Professional Use) devices under a single 510(k) number as referenced above and we have determined that these two devices are 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). Please note that the consolidation of these two devices under a single 510(k) number, K994006, does not change the fact that there are two separate and different intended uses for these devices, one for professional use and one for home use by prescription, and two different sets of quality control recommendations for the two devices. 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.

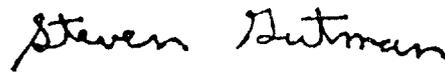
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

Page 2

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" (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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 994006

Device Names: Avocet AcuSure System for Patient Self-Testing and Avocet AcuSure Pro System for Professional Use.

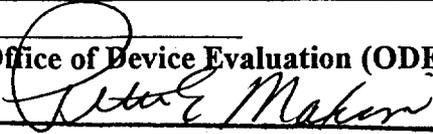
Indications For Use:

The AcuSure System for Patient Self-Testing is intended for the quantitative prothrombin time testing of fresh, capillary whole blood by selected and suitably trained patients or their caregivers on the prescription of the treating physician. The AcuSure System for Patient Self-Testing is for the monitoring of patients on oral anticoagulant therapy and not intended to be used for screening purposes.

The AcuSure Pro System for Professional Use is intended for the quantitative prothrombin time testing of fresh, capillary whole blood by healthcare professionals. The AcuSure Pro System is for the monitoring of patients on oral anticoagulant therapy and not intended to be used for screening purposes.

(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 Clinical Laboratory Devices
510(k) Number K994006

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

000336