

SEP 30 1998



1696 Dell Ave., Campbell, CA 95008 • 408/374-7262 • Fax 408/374-7822

Avocet Medical, Inc.  
 Avocet<sub>PT</sub> System  
 510(k) Premarket Notification

### 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.  
 1696 Dell Avenue  
 Campbell, CA 95008  
 (408) 374-7262 (phone)  
 (408) 374-7822 (fax)

Contact person: Judith Blunt

Date prepared: June 8, 1998
  2. **Device name**

Common or Usual Name: Prothrombin Time Test (INR)

Classification Name: Prothrombin Time Test

Trade or Proprietary Name: Avocet<sub>PT</sub>
  3. **Predicate device**

The Boehringer Mannheim Coaguchek™ System: device for testing Prothrombin Time and INR in whole blood.
  4. **Device description**

The Avocet<sub>PT</sub> is a membrane-based, dry-reagent system for use with fresh capillary or venous whole blood, and citrated venous whole blood or citrated plasma. The system uses an 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



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prothrombin-time-equivalent parameter that is converted to an international normalized ratio (INR) value.

5. Intended use:

The Avocet<sub>PT</sub> is an *in vitro* diagnostic system that provides a quantitative prothrombin time result, expressed as an International Normalized Ratio (INR). It is intended for use by health care professionals in monitoring patients who are on warfarin-type (coumarin) anticoagulation therapy.
6. Comparison to predicate device

The Avocet<sub>PT</sub> 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 CoaguChek™, manufactured by the Boehringer Mannheim Corporation. Both products are prothrombin time devices, have the same intended use and serve the same professional, point-of-care market. The Avocet<sub>PT</sub> and the CoaguChek both measure the extrinsic coagulation pathway, expressed as an International Normalized Ratio. Both products measure the elapsed time between the start of the reaction and the formation of thrombin using a dry reagent thromboplastin. While CoaguChek measures this formation as expressed through the conversion of fibrinogen (a thrombin substrate) to fibrin via the motion of magnetic particles, the Avocet<sub>PT</sub> measures this formation as expressed through the conversion of (Tos-Gly-Pro-Arg)<sub>2</sub>-Rhodamine 110 (a thrombin substrate) to free Rhodamine via a change in fluorescence.
7. Summary of performance data

The accuracy of the Avocet<sub>PT</sub> was compared to the CoaguChek and a reference method in field studies and found to be equivalent ( $r > 0.95$ ). Precision and linearity evaluations were done on the Avocet<sub>PT</sub> and found to be acceptable. Additional testing of interfering substances, hematocrit, RBC abnormalities and factor deficiencies were performed and the results are reflected in the product labeling.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 30 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Judith Blunt  
Director of Regulatory Affairs  
and Quality Assurance  
Avocet Medical Incorporated  
1696 Dell Avenue  
Campbell, California 95008

Re: K980839/S1  
Trade Name: Avocet<sub>PT</sub>  
Regulatory Class: II  
Product Code: JPA  
Dated: July 2, 1998  
Received: July 6, 1998

Dear Ms. Blunt:

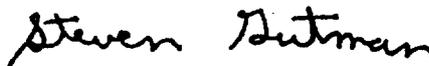
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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

March 12, 1998

PREMARKET NOTIFICATION  
INDICATIONS FOR USE FORM

Page 1 of 1

510(K) Number: Not known

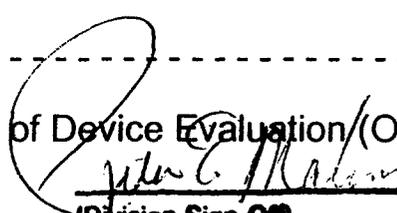
Device Name: Avocet<sub>PT</sub> System

The Avocet<sub>PT</sub> is an *in vitro* diagnostic system that provides a quantitative prothrombin time result, expressed as an International Normalized Ratio (INR). It uses fresh capillary whole blood, citrated venous whole blood or citrated venous plasma samples. It is intended for use by health care professionals in monitoring patients who are on warfarin-type (coumarin) anticoagulation therapy.

This does not differ substantially from the intended use of the Boehringer Mannheim CoaguChek (predicate device).

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 Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

1980839

Prescription Use

OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)