K050743

JUN 6 - 2005

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 determination of substantial equivalence
1. Submitter's name, address, contact:	Farallon Medical Inc. 3521 Investment Blvd., Suite 1 Hayward, CA 94545 Phone: 510-785-0800 FAX: 510-785-0888 Contact person: Mr. James McKinley Date Prepared: January 31, 2005
2. Device name:	Device Name: Immedia Prothrombin Time System Proprietary/Trade Name: Immedia Prothrombin Time System Common Name: Prothrombin Time Test
3. Predicate device:	The Roche CoaguChek® system: Device for testing Prothrombin Time and INR in whole blood.
4. Device description:	The Immedia™ Prothrombin Time System measures the Prothrombin Time (PT) of fresh capillary whole blood. The test is performed by inserting a test strip into the meter and applying a drop of blood to the sample receptacle of the test strip. The meter automatically performs the PT test and the result is displayed as International Normalized Ratio (INR) and seconds (PT). The meter automatically stores all test results in memory. The device is powered by batteries and/or AC adapter. The disposable strip contains a rotating, spoked wheel that draws the sample into the reaction well after it is applied to the sample receptacle. The spokes rotate across the path of an infrared light beam and mix the liquid sample with the thromboplastin which is dried in the reaction well. When the sample clots, the clot is picked up by the spokes, interrupting the path of the infrared light beam that is detected by the meter. A separate Calibration Strip is used for inputting the calibration data. High Control and Low Control Strips are also provided for quality control purposes.

5. Intended use:	The Immedia system is an *in vitro* diagnostics system that provides a quantitative ProthrombinTime test result for fresh capillary whole blood expressed in seconds and 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. This device is not intended to be used for screening purposes.
6. Comparison to Predicate device	The Immedia system is substantially equivalent in design, materials and intended use to other products that measure Prothrombin Time in human blood. Most notably, it is substantially equivalent to the CoaguChek S®, manufactured by Roche Diagnostics.
7. Summary of performance data	The accuracy of the Immedia device was compared to the CoaguChek S and a reference method in field studies and found to be equivalent ($r>0.90$). Precision and linearity evaluations were performed on the Immedia device and the results were found to be acceptable. Additional testing on interfering substances, and hematocrit were performed and the results are reflected in the product labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 6 - 2005

Mr. James McKinley
President and CEO
Farallon Medical, Inc.
3521 Investement Boulevard
Suite 1
Hayward, California 94545

Re: k050243
Trade/Device Name: Immedia Prothrombin Time System
Regulation Number: 21 CFR § 864.5425
Regulation Name: System, multipurpose for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: May 2, 2005
Received: May 3, 2005

Dear Mr. McKinley:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. 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,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050243

Device Name: Immedia Prothrombin Time System

Indications For Use: The Immedia System is an in vitro diagnostic device that provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professional at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy. The device is not intended to be used for screening purposes.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

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