

K981038

APR 16 1998

Section 3
Coamatic® Factor VIII - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

Carol Marble
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Contact Persons:

Carol Marble
Phone: (781) 861-4467

Summary Prepared:

March 18, 1998

Name of the device:

Coamatic® Factor VIII

Classification name(s):

864.7290 Factor Deficiency Test Class II
81GGP Test, Qualitative and Quantitative Factor Deficiency

Identification of predicate device(s):

Coatest® Factor VIII K833892

Description of the device/intended use(s):

Coamatic® Factor VIII is an *in vitro* diagnostic test for the quantitative determination of Factor VIII activity in human citrated plasma using manual, microplate and automated methods. The measurement of Factor VIII is used as an aid in the identification of factor VIII deficiency or to monitor patients on replacement therapy as well as for potency estimation of FVIII concentrates.

Statement of How the Technological Characteristics of the Device Compare to the Predicate Device:

Coamatic® Factor VIII uses the same general test principle as the predicate Coatest® Factor VIII and is substantially equivalent in performance, intended use, and safety and effectiveness.

Summary of Performance Data:

In a method comparison study evaluating 69 plasma samples, the correlation (r) of the new Coamatic® Factor VIII on a Cobas Mira S as compared to the predicate Coatest® Factor VIII using a manual test tube method was 0.99.

Within run precision assessed over multiple runs gave a CV of 1.87% (at a Factor VIII concentration of 1.0 IU/mL), 2.57% (at a Factor VIII concentration of 0.21 IU/mL) and 2.76% (at a Factor VIII concentration of 0.025 IU/mL).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 16 1998

Carol Marble
.Senior Regulatory Affairs Specialist
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02173-3190

Re: K981038
Coamatic® Factor VIII
Regulatory Class: II
Product Code: GGP
Dated: March 18, 1998
Received: March 19, 1998

Dear Ms. Marble:

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 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.

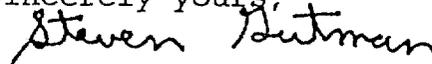
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

Indications for Use Statement

510(k) Number (if known): _____

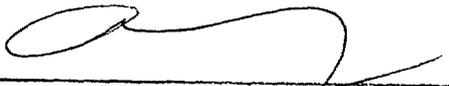
Device Name: Coamatic® Factor VIII

Indications for Use:

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(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

 K0181038

Prescription Use _____
(Per 21 CFR 801.019)

OR

Over-The-Counter Use _____