K983178

NOV 3 1998

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

Submitted by:

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Summary Prepared:

September 10, 1998

Name of the device:

Coamatic® Heparin

Classification name(s):

864.7525	Heparin Assay	Class II
81KFF	Assay, Heparin	

Identification of predicate device(s):

K980242 IL Test™ Heparin

Description of the device/intended use(s):

Coamatic® Heparin is an *in vitro* diagnostic test for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma using automated and microplate methods.

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

The new Coamatic® Heparin is based on a synthetic chromogenic substrate and Factor Xa inactivation, as is the predicate device: IL Test™ Heparin, and is substantially equivalent in its performance, intended use and safety and effectiveness.

Summary of Performance Data:

The results from comparative studies of Coamatic® Heparin on different methods vs. IL Test™ Heparin on an ACL 300 using samples from patients treated with UFH and LMWH are shown below:

Application	n	Slope	Intercept	r
Cobas Mira	87	1.04	-0.01	0.98
Microplate	70	1.00	0.02	0.97
ACL 300	62	1.02	0.01	0.98
ACL Futura	113	0.97	0.01	0.97
MLA Electra	80	1.01	0.00	0.97

Summary of Performance Data (Continued):

The results from additional comparative studies of Coamatic® Heparin on other methods vs. IL Test™ Heparin on an ACL 300 using normal plasmas and pooled plasmas spiked with UHF heparin are shown below:

Application	n	Slope	Intercept	r
Sysmex 6000	30	0.91	0.06	0.99
AMAX	30	0.97	0.03	0.99
Hitachi 911	30	0.98	0.01	0.99
Hitachi 917	30	1.00	0.02	0.98

Precision data summarized below was obtained with the microplate method using unfractionated heparin (UFH) and low molecular weight heparin (LMWH):

Microplate Method:

Mean Concentration	Within Run %CV	Between Run %CV	Total %CV
0.7 IU/mL UFH	2.8	1.2	2.8
0.4 IU/mL UFH	3.4	1.5	3.7
0.7 IU/mL LMWH	3.6	2.8	4.4
0.4 IU/mL LMWH	2.4	2.3	3.2

NOTE: Instrument-specific precision results are available in the application sheets.

Instrumentation Laboratory

September 8, 1998

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
[AS REQUIRED BY 21 CFR 807.87(j)]

I certify that, in my capacity at Instrumentation Laboratory Company, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

William Wood
Signature

William Wood
Name

IL Director of Regulatory Affairs/Quality Assurance
Title

9/8/98
Date

K983178
Premarket Notification 510(k) Number
Coamatic® Heparin

Instrumentation Laboratory Company
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 3 1998

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02173-3190

Re: K983178
Trade Name: Coamatic® Heparin
Regulatory Class: II
Product Code: KFF
Dated: September 10, 1998
Received: September 11, 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 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 Gutman

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): K983178

Device Name: Coamatic® Heparin

Indications for Use:

Coamatic® Heparin is an *in vitro* diagnostic test for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma using automated and microplate methods. The amount of UFH or LMWH is determined from the anti-FXa activity expressed by the [AT*Heparin] complex formed in plasma.

Heparin is the most frequently used antithrombotic drug. The biological activity of this sulphated glycosaminoglycan resides in its ability to accelerate (up to 2000-fold) the inhibitory effect of antithrombin on coagulation proteases.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maderi

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983178

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)