

K980242

MAR 19 1998

Section 3
IL Test™ Heparin - 510(k) SUMMARY
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

January 22, 1998

Name of the device:

IL Test™ Heparin

Classification name(s):

864.7525 Heparin Assay Class II
81KFF Assay, Heparin

Identification of predicate device(s):

K935212 IL Test™ Heparin Xa

Description of the device/intended use(s):

IL Test™ Heparin is an in vitro diagnostic test for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human plasma. It is an automated heparin assay based on a synthetic chromogenic substrate and Factor Xa inactivation.

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

The new IL Test™ Heparin uses the same test principle as the predicate IL Test™ Heparin Xa and is substantially equivalent in performance, intended use and safety and effectiveness.

Summary of Performance Data:

In method comparison studies that included samples from patients treated with UFH and LMWH, the correlation (r) of the new IL Test™ Heparin to the predicate IL Test™ Heparin Xa on the ACL 300 was 0.988 (n=98) and on the ACL Futura was 0.989 (n=91).

On the ACL 300, within run precision accessed over multiple runs using 2 levels of the 4th Heparin International Standard, UFH gave a CV of 1.84% (at a mean of 0.77 U/mL) and 7.76% (at a mean of 0.23 U/mL). On the ACL Futura, within run precision accessed over multiple runs using 2 levels of the 4th Heparin International Standard, UFH gave a CV of 4.06% (at a mean of 0.81 U/mL) and 14.27% (at a mean of 0.21 U/mL).



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 19 1998

Carol Marble
Senior Regulatory Affairs Specialist
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113 Hartwell Avenue
Lexington, Massachusetts 02173-3190

Re: K980242
IL Test™ Heparin
Regulatory Class: II
Product Code: KFF
Dated: January 22, 1998
Received: January 23, 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.

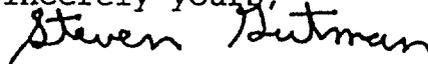
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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): K980242

Device Name: IL Test™ Heparin

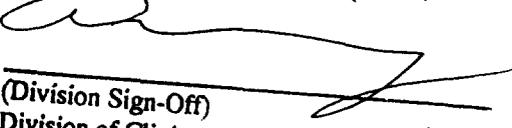
Indications for Use:

IL Test™ Heparin is an *in vitro* diagnostic test for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human plasma. It is an automated heparin assay based on a synthetic chromogenic substrate and Factor Xa inactivation.

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. In recent years, it has been shown that LMWH, besides being as useful therapeutically as UFH, also has a longer half-life.

(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 K980242

Prescription Use
(Per 21 CFR 801.019)

OR Over-The-Counter Use