510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

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2. General Information

Trade Name	Thrombelastograph® Coagulation Analyzer TEG® - 5000 Series
Common / Usual Name	Thrombelastograph Instrument
Classification Name	Multipurpose System for In Vitro Coagulation Studies
Identification of Equivalent Devices	Thrombelastograph® Coagulation Analyzer – 3000S, Haemoscope Corp. (K954137)

3. Device Description

The TEG - 5000 Series Analyzer consists of a two-column TEG instrument, a computer interface module, software, and disposable sample cups and pins. The TEG measures the clot's physical property by the use of a special stationary cylindrical cup that holds the blood and is oscillated. A pin is suspended in the blood by a torsion wire and is monitored for motion. The torque of the rotation cup is transmitted to the immersed pin only after fibrin-platelet bonding has linked the cup and pin together. The strength of these fibrin-platelet bonds affects the magnitude of the pin motion, such that strong clots move the pin directly in phase with the cup motion. The magnitude of the output is, therefore, directly related to the strength of the formed clot. As the clot retracts or breaks apart, these bonds are broken and the transfer of cup motion is diminished.

4. Intended Use

The TEG - 5000 Series Analyzer is intended to be used to provide a quantitative and qualitative indication of the coagulation state of a blood sample by monitoring, measuring, analyzing and reporting coagulation parameter information. The Thrombelastograph (TEG) Coagulation Analyzer TEG - 5000 Series records the kinetic changes in a sample of whole blood, plasma or platelet rich-plasma as the sample clots, retracts and/or lyses (breaks apart).

Results from the TEG analyzer should not be the sole basis for a patient diagnosis; TEG results should be considered along with a clinical assessment of the patient's condition and other coagulation laboratory tests. For Professional Use Only.

5. *Technological Characteristic Comparisons*

The Thrombelastograph Coagulation Analyzer TEG - 5000 Series is substantially equivalent to the Haemoscope Corporation Thrombelastograph Coagulation Analyzer – 3000S (K954137). Compared to the predicate device, the TEG - 5000 Series Analyzer has the same intended use, principles of operation and function as the TEG - 3000S Analyzer. There are no technological differences between the two TEG analyzer families. The TEG - 5000 Series Analyzer, a modified version of the Haemoscope TEG 3000S Analyzer, offers instructions and software for determining the functional fibrinogen level of a clot sample. In addition, the TEG - 5000 Series offers an improved sample cup placement and retrieval system, and an improved software menu structure, enhancing ease of use and user safety.

6. *Summary of Studies*

Comparative performance testing and software validation testing was performed to demonstrate that the TEG - 5000 Series analyzer meets established design specifications and performance requirements. The test results confirmed that, despite differences, the TEG - 5000 Series Analyzer meets established design specifications and performs as well as the predicate device. No new questions of safety or effectiveness were raised.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission support a substantial equivalence determination and, therefore, clearance of the 510(k) premarket notification for the Thrombelastograph Coagulation Analyzer TEG - 5000 Series.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2000

Eli Cohen, Ph.D.
President and CEO
Haemoscope Corporation
7855 Gross Point Road, Unit G-4
Skokie, Illinois 60077

Re: K993678
Trade Name: Thrombelastograph® Coagulation Analyzer TEG® 5000 Series
Regulatory Class: II
Product Code: JPA
Dated: April 3, 2000
Received: April 4, 2000

Dear Dr. Cohen:

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" (21CFR 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): **K993678**

Device Name:
Thrombelastograph® (TEG®) Coagulation Analyzer TEG® – 5000 Series

Indications for Use:

The Thrombelastograph (TEG) Coagulation Analyzer TEG - 5000 Series is a non-invasive diagnostic instrument designed to monitor and analyze the coagulation state of a blood sample in order to assist in the assessment of patient clinical hemostasis conditions. The TEG is indicated for use with adult patients where an evaluation of their blood coagulation properties is desired. Coagulation evaluations are commonly used to assess clinical conditions such as post-operative hemorrhage and / or thrombosis during and following cardiovascular surgery, organ transplantation, trauma, and cardiology procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription ✓

Peter E Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993678