

SEP - 1 2004

510(k) Summary

K041502

Submitter's Name / Contact Person

Haemoscope Corporation
5693 West Howard Street
Niles IL 60714

Eli Cohen, Ph.D.
President and CEO
Tel: (847) 588-0453 / (800) 438-2834

General Information

Device Trade Name	Thrombelastograph® (TEG®) Platelet Mapping™ Assay
Common / Usual Name	Platelet Aggregation Assay
Classification Name	Automated Platelet Aggregation System
Classification	This device has been classified by the Hematology and Pathology Devices Panel (81) into Class II (21 CFR 864.5700).

Device Description

The TEG Platelet Mapping Assay consists of a set of blood modifiers, ADP and AA platelet agonists together with ActivatorF, which when used on a heparinized blood sample can measure the inhibition of platelet function.

Intended Use

The TEG Platelet Mapping Assay is intended for use with the Thrombelastograph (TEG) Hemostasis Analyzer to assess platelet function in patients who have received platelet inhibiting drugs such as aspirin, clopidogrel, abciximab, tirofiban, or eptifibatide. For Professional Use Only.

Predicate Devices

The TEG Platelet Mapping Assay is substantially equivalent to the following devices:

- Thrombelastograph® Coagulation Analyzer (TEG®) - 5000 Series
- Chrono-log Corp. Optical Aggregation Systems and Reagents

Summary of Studies

The TEG Platelet Mapping Assay was subjected to testing to verify the reliability of the assay and to demonstrate substantial equivalence. Test results demonstrate that the TEG reliably detects a reduction in platelet function (aggregation) in the presence of anti-platelet drugs, and that the TEG measurements correlate well with the optical aggregometry method.

Conclusion

The data and information provided in this submission demonstrate substantial equivalence and support clearance of the 510(k) premarket notification for the TEG Platelet Mapping Assay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Eli Cohen, Ph.D.
President and CEO
Haemoscope Corporation
5693 West Howard Street
Niles Illinois 60714

SEP - 1 2004

Re: k041502
Trade/Device Name: Thrombelastograph® (TEG®) Platelet Mapping™ Assay
Regulation Number: 21 CFR § 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: II
Product Code: JOZ
Dated: June 4, 2004
Received: June 7, 2004

Dear Dr. Cohen:

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.

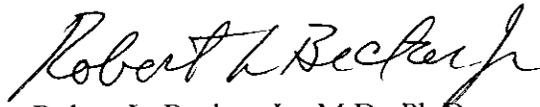
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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.

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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 (301) 594-3084. 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/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Robert L. Becker, Jr.".

Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

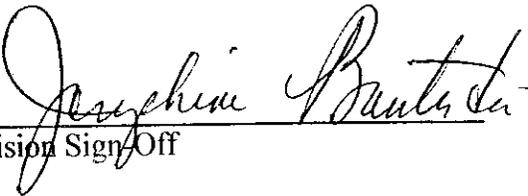
Enclosure

510(k) Number (if known): K041502

Device Name: Thrombelastograph® (TEG®) Platelet Mapping™ Assay

Indications For Use:

Intended Use: The TEG® Platelet Mapping Assay is intended for use with the Thrombelastograph (TEG) Hemostasis Analyzer to assess platelet function in patients who have received platelet inhibiting drugs such as aspirin, clopidogrel, abciximab, tirofiban, or eptifibatide.


Division Sign Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K041502

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)