SEP - 1 2004

510(k) Summary

K041502

Submitter’s Name / Contact Person
Haemoscope Corporation
5693 West Howard Street
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Eli Cohen, Ph.D.
President and CEO
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General Information

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

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.
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.
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" (21 CFR 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,

[Signature]

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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use [ ] OR Over-The-Counter Use [ ]
(Per 21 CFR 801.109) (Optional Format 1-2-96)