



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Patricia Franks  
Assistant Director, Regulatory Affairs  
Helena Laboratories  
1530 Lindbergh Drive  
P.O. Box 752  
Beaumont, Texas 77704-0752

FEB 14 2003

Re: k023761  
Trade/Device Name: Plateletworks®  
Regulation Number: 21 CFR § 864.5700  
Regulation Name: Automated Platelet Aggregation System  
Regulatory Class: II  
Product Code: JOZ  
Dated: January 13, 2003  
Received: January 14, 2003

Dear Ms. Franks:

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.

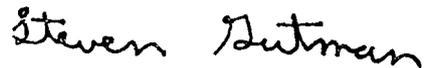
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

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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 black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

**Indications for Use:**

510(k) Number (if known):

Device Name: Plateletworks®

Plateletworks (K990398) is an in vitro diagnostic screening assay for the determination of % platelet aggregation in fresh whole blood samples taken during cardiac interventional procedures as measured by a change in platelet count due to activation of functional platelets. It may be used at the point-of-care on the Ichor or Coulter hematology analyzers as a screening tool for the detection of trends suggestive of platelet dysfunction. Any abnormal baseline or otherwise suspicious result would require repeating the Plateletworks test procedure and/or further additional investigation with more definitive test methods, including conventional platelet aggregometry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Signature]*  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K 023761

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use