



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 28 2001

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

Re: K012723
Trade/Device Name: Collagen for Plateletworks™
Regulation Number: 21 CFR § 864.5700
Regulation Name: System, Automated Platelet Aggregation
Regulatory Class: II
Product Code: JOZ
Dated: August 13, 2001
Received: August 15, 2001

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

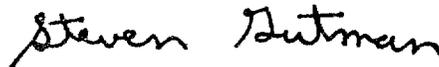
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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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 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,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

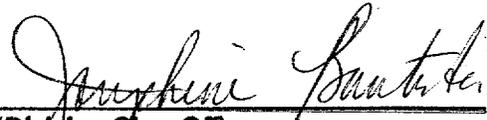
Enclosure

510(k) Number (if known): K012723

Device Name: Plateletworks™

Indications for Use:

Plateletworks 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 hematology analyzer 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.



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012723

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)