



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

HemoCue, Incorporated  
c/o R.J. Slomoff  
9229 Cranford Drive  
Potomac, Maryland 20854

**AUG 25 2003**

Re: k032203  
Trade/Device Name: HemoCue® Hb 201+ System  
Regulation Number: 21 CFR § 864.5620  
Regulation Name: Automated Hemoglobin System  
Regulatory Class: II  
Product Code: GKR  
Dated: July 14, 2003  
Received: July 31, 2003

Dear Mr. Slomoff:

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 black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

510(k) Number: K032203

Device Name: **HemoCue® Hb 201+ System**

Indications For Use:

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood.

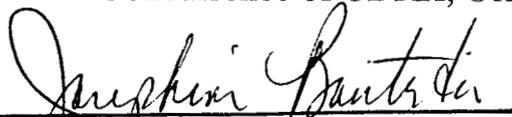
The HemoCue® Hb 201 Microcuvettes are intended for use in the HemoCue® Hb 201<sup>+</sup> analyzer. The HemoCue 201 system is used for the quantitative determination of hemoglobin in blood using a specially designed analyzer, the HemoCue Hb 201<sup>+</sup> analyzer, and specially designed microcuvettes the HemoCue Hb 201 Microcuvettes. The HemoCue Hb 201<sup>+</sup> analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

The reagents/microcuvettes and the analyzer form an analytical system. The HemoCue Hb 201<sup>+</sup> analyzer is only to be used together with HemoCue Hb 201 microcuvettes. The use of any other device in the HemoCue Hb 201<sup>+</sup> analyzer except the HemoCue Hb 201 microcuvettes is neither supported nor recommended by HemoCue, and could give erroneous results with serious clinical consequences.

The HemoCue Hb 201 microcuvettes are for in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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Division Sign-Off

(Optional Format 3-10-98)

**Office of In Vitro Diagnostic Device  
Evaluation and Safety**

510(k) K032203