



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 13 2003

Dr. Lynne Hamilton  
Regulatory Affairs  
Radox Laboratories, Ltd.  
Biochemical Manufacturers  
Ardmore, Diamond Road  
Crumlin, Co. Antrim  
United Kingdom BT29 4QY

Re: k023763  
Trade/Device Name: Fructosamine, Frutosamine Calibrator, Fructosamine Controls  
Regulation Number: 21 CFR 864.7470  
Regulation Name: Glycosylated hemoglobin assay  
Regulatory Class: Class II  
Product Code: LCP; JIT; JJX  
Dated: November 7, 2002  
Received: November 8, 2002

Dear Dr. Hamilton:

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.

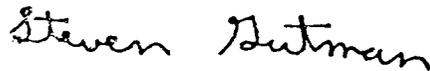
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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" (21CFR Part 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,

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 (if known) **NOT KNOWN**

Device Name **Fructosamine, Fructosamine Calibrator, Fructosamine Controls**

K023763

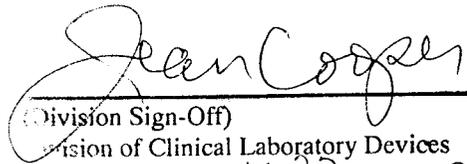
**Indications For Use :**

Fructosamine

The Randox Laboratories Limited Fructosamine test kit is an *in vitro* diagnostic enzymatic assay for the quantitative determination of glycated protein (fructosamine) in human serum or plasma.

Measurement of glycated serum protein is representative of the mean blood glucose levels over the preceding 2-3 weeks.

For *in vitro* diagnostic use only.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K023763

Fructosamine Calibrator

For calibration of the Fructosamine assay.

For *in vitro* diagnostic use only.

Fructosamine Controls (Level 1 and Level 3)

To monitor the performance of the Fructosamine assay.

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)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  \_\_\_\_\_  
(Optional format 1-2-96)