



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**MAR 21 2005**

Mr. Neil B. Stringer  
Managing Director  
Cheshire Diagnostics Ltd.  
Management Centre, Inward Way  
Ellesmere Port  
Cheshire  
United Kingdom CH 65 3EN

Re: k020695

Trade/Device Name: QA $\beta_2$ A IgG Elisa Kit AP  
Regulation Number: 21 CFR 866.5660  
Regulation Name: Multiple autoantibodies immunological test system  
Regulatory Class: Class II  
Product Code: MSV  
Dated: March 1, 2002  
Received: March 4, 2002

Dear Mr. Stringer:

This letter corrects our substantially equivalent letter of April 19, 2002 regarding the QA $\beta_2$ A IgG Elisa Kit AP in which the wrong product code was used.

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 (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 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.

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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 forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. 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/dsrna/dsrnarnain.htm>

Sincerely yours,



Robert L. Becker, Jr., M.D., PhD

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K020695

Device Name: QA $\beta$ <sub>2</sub>A IgG Elisa Kit AP

Indications for Use: The Cheshire Diagnostics Limited QA $\beta$ <sub>2</sub>A IgG Elisa Kit is a semi quantitative enzyme linked immunoassay for the detection of the IgG isotype autoantibody to  $\beta$ <sub>2</sub>-Glycoprotein-I in human serum.

The presence of  $\beta$ <sub>2</sub>-GPI antibodies can be used in conjunction with other serological tests and clinical findings to aid in the assessment of the risk from thrombosis in patients with Systemic Lupus Erythematosus or other Lupus like disorders.

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### Concurrence of CDRH, Office of Device Evaluation (ODE)

*Souman S. Altaie*

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K020695

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-the-counter Use

(Optional Format 1-2-96)