Arrows

K972382

ARROWS Co., Ltd.

SEP 14 1998

2-7-50 Nishimiyahara, Yodogawa-ku. Osaka 532 Japan
Tel : +81 6 350 0918 Fax : 81 6 350 0892

September 25, 1997

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland and 20850 USA

Premarket Notification [510(K)] Number K972382

Attention : Document Mail Clerk

Dear Sirs :

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ARROWS Co., Ltd. is requesting marketing clearance for in vitro diagnostic use of UB analyzer UA-2, its reagent kit and the bilirubin control to be manufactured by ARROWS Co., Ltd. Our UB analyzer UA-2 represents an apparatus for measuring unbound bilirubin as well as total bilirubin in newborns quantitatively. The UB analyzer UA-2 provides effective means for the rapid and accurate determination of unbound bilirubin in the serum of newborns by an enzymatic method utilizing Glucose Oxidase (GOD) and Peroxidase (POD).

The UB analyzer UA-2 is designed to determine both the total and unbound bilirubin concentrations in neonatal serum. These concentrations of bilirubin can be used by the physician for clinically assessing jaundiced neonates and for the possible association with bilirubin encephalopathy.

5k-1

Submitter's Name : ARROWS Co., Ltd.
Address : 2-7-50 Nishimiyahara, Yodogawa-ku, Osaka 532 Japan
Telephone Number : +81 6 350 0918
Fax Number : +81 6 350 0892
Contact Person : Yoshimasa Ogoshi

Proprietary Name : UB analyzer UA-2
UB analyzer reagent kit and bilirubin control

Common/Usual Name : Bilirubinometer for the detection of total and unbound concentrations of bilirubin in neonatal serum, its reagent kit, and bilirubin control

Classification : II

Classification Name : DIAZO COLORIMETRY, BILIRUBIN

Substantial Equivalence :
UB analyzer UA-2 is similar in design and function to UB ANALYZER , MODEL UA-1 / REAGENT KIT / BILIRUBIN CON. which was approved with Premarket notification 510(K) number K871115 by FDA and marketed in USA by LABO SCIENCE-USA INC. We had been the original manufacturer of UB ANALYZER , MODEL UA-1 / REAGENT KIT / BILIRUBIN CON. and modified this device in design, adopting the state-of-the-art technology.
As the comparison table and scientific literature show, the modifications are not substantial and do not affect any safety, effectiveness and the intended use of the device.

The description of the device :
The UB analyzer UA-2 is designed to determine both the total and unbound bilirubin concentrations in neonatal serum quantitatively with rapidity and accuracy. Determined concentrations of total bilirubin and unbound bilirubin are digitally displayed on LCD and printed out with UB/TB ratio and determined date. These concentrations of bilirubin can be used by the physician for clinically assessing jaundiced neonates and for the possible association with bilirubin encephalopathy.

The intended use of the device :

The UB analyzer UA-2 is designed to measure quantitative concentrations of total bilirubin and unbound bilirubin in neonatal serum with rapidity and accuracy by the enzymatic method. These concentrations of bilirubin can be used by the physician for clinically assessing jaundiced neonates and for the possible association with bilirubin encephalopathy.

The technological characteristics of the device compared to the predicative device :

The UB analyzer UA-2 was modified in design of UB ANALYZER UA-1 adopting the state -of -the art technology. As "Comparison on the specifications of UB ANALYZER UA-1 and UB analyzer UA-2" shows, the technological characteristics of the UB analyzer UA-2 are basically the same with the predicative device, UB ANALYZER UA-1.

The followings are the modified technological characteristics :

1. Display was changed from LED to LCD (liquid crystal display).
2. As printer was built in with UB analyzer UA-2, the measurement results are automatically printed out together with LCD display.

If you have any question or require any further information, please fell free to contact me at fax +81 350 0892.

Sincerely yours,

Yoshimasa Ogoshi
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 14 1998

Nobuo Hisa
Trading Manager
Arrows Co., Ltd.
2-7-50 Nishimiyahara, Yodogawa-ku
Osaka 532 Japan

Re: K972382
UB Analyzer UA-2, Reagent Kit, and Bilirubin Control
Regulatory Class: I, II
Product Code: CIG, JJX
Dated: August 28, 1997
Received: August 31, 1997

Dear Mr. Hisa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

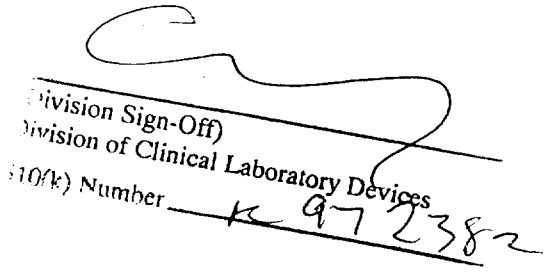
Steven Gutman

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

INDICATION FOR USE STATEMENT

UB analyzer UA-2 and its exclusive reagent kit are designed to determine both total and unbound bilirubin concentration in neonatal serum using exclusive reagent kit, "UB TEST." The total bilirubin and unbound bilirubin concentration in neonatal serum can be used to provide the physician with additional information in the clinical assessment of jaundiced neonates and the possible risk of bilirubin encephalopathy.



Prescription Use