April 13, 2018

BioSystems S.A.
Teresa Maria Cortes
Quality Assurance Manager
Costa Brava, 30.
08030 Barcelona
Spain

Re: K170901
Trade/Device Name: ALBUMIN, ALKALINE PHOSPHATASE (ALP)-AMP, GLUCOSE-HEXOKINASE, BA400
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin test system
Regulatory Class: Class II
Product Code: CIX, CJE, CFR, JJE
Dated: March 9, 2018
Received: March 12, 2018

Dear Teresa Maria Cortes:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170901

Device Name
BA400, ALBUMIN, ALKALINE-PHOSPHATASE (ALP) - AMP, GLUCOSE-HEXOKINASE

Indications for Use *(Describe)*

BA400

The BA400 analyser is used to determine analyte concentrations by in vitro biochemical and turbidimetric measurements of human samples of serum, urine, plasma, cerebrospinal fluid or total blood.

This device is intended to replace manual analytical procedures by performing automatically various steps such as pipetting, heating, and measuring color intensity.

ALBUMIN

Reagent for the measurement of albumin concentration in human serum or plasma. The obtained values are useful as an aid in the evaluation of protein synthesis of the liver in the chronic liver diseases and for the study of the nutritional status.

This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

ALKALINE PHOSPHATASE (ALP) – AMP

Reagent for the measurement of alkaline phosphatase (ALP)-AMP concentration in human serum or plasma. The obtained values are useful as an aid in the diagnosis and treatment of hepatobiliary and bone diseases with impaired osteoblastic activity diseases.This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

GLUCOSE-HEXOKINASE

Reagent for the measurement of glucose concentration in human serum, plasma, urine or cerebrospinal fluid. The obtained values are useful as an aid in the diagnosis and monitoring of the diabetes mellitus.

This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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