May 2, 2019

BioSystems S.A.
Noelia Gil
Quality Assurance Specialist
Costa Brava, 30
Barcelona, 08030
Spain

Re: K182474
Trade/Device Name: alpha-AMYLASE DIRECT
alpha-AMYLASE EPS
alpha-AMYLASE PANCREATIC
BILIRUBIN DIRECT
BILIRUBIN TOTAL
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ, CIG
Dated: March 29, 2019
Received: April 1, 2019

Dear Noelia Gil:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or post marketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

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)*
K182474

Device Name
alpha-AMYLASE DIRECT, alpha-AMYLASE EPS, alpha-AMYLASE PANCREATIC, BILIRUBIN (DIRECT), BILIRUBIN (TOTAL)

Indications for Use *(Describe)*

alpha-AMYLASE DIRECT: Reagent for the measurement of alpha-amylase concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis of acute and chronic pancreatitis.This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

alpha-AMYLASE EPS: Reagent for the measurement of alpha-amylase concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis of acute and chronic pancreatitis. This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

alpha-AMYLASE PANCREATIC: Reagent for the measurement of pancreatic α-amylase concentration in human serum, plasma or urine. The obtained values are useful as an aid in the diagnosis of acute and chronic pancreatitis. This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

BILIRUBIN DIRECT: Reagent for the measurement of direct bilirubin concentration in human serum or plasma. Measurements of the levels of bilirubin are used in the diagnosis and treatment of liver, hemolytic hematological and metabolic disorders, including hepatitis and gall bladder block. This reagent is for use in the BioSystems BA analyzers. Only for in vitro use in the clinical laboratory.

BILIRUBIN TOTAL: Reagent for the measurement of total bilirubin concentration in human serum or plasma. Measurements of the levels of bilirubin are used in the diagnosis and treatment of liver, hemolytic hematological and metabolic disorders, including hepatitis and gall bladder block. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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