U.S. FOOD & DRUG ADMINISTRATION

May 20, 2019

Abbott Laboratories
Mark Littlefield
Section Manager, Regulatory Affairs
Dept. 09va Lc-2
1920 Hurd Drive
Irving, TX 75038

Re: K981653
Trade/Device Name: Amy
Regulation Number: 21 CFR 862.1070
Regulation Name: Amylase test system
Regulatory Class: Class II
Product Code: JFJ
Dated: May 8, 1998
Received: May 11, 1998

Dear Mark Littlefield:

This letter corrects our substantially equivalent letter of August 28, 1998.

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 postmarketing 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,

Kellie B. Kelm -S

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Amylase

Indications For Use:

The Amylase assay is used for the quantitation of amylase in serum, plasma, or urine on the AEROSET System. Amylase measurements are used primarily for the diagnosis and treatment of pancreatitis (inflammation of the pancreas).

AH for AWM

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981653

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K981653

510(k) Summary

Submitter's Name/Address
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Irving, Texas 75038

Contact Person
Mark Littlefield
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ADD Regulatory Affairs
(972) 518-6062
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Date of Preparation of this Summary: May 8, 1998

Device Trade or Proprietary Name: Amy

Device Common/Usual Name or Classification Name: Amylase

Classification Number/Class: 75JFJ/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____.

Test Description:

Amylase is an *in vitro* diagnostic assay for the quantitative determination of amylase in serum, plasma, or urine. The Amylase assay is a clinical chemistry assay. The amylase in the sample hydrolyzes the 2-chloro-4-nitrophenyl-α-D-maltotrioside (CNPG3) to release 2-chloro-4-nitrophenol (CPNP) and form 2-chloro-4-nitrophenyl-α-D-maltoside (CNPG2), maltotriose (G3), and glucose (G). The rate of formation of the 2-chloro-4-nitrophenol is measured as an increase in the absorbance at 405 nm and is directly proportional to the activity of amylase present in the sample.

Substantial Equivalence:

The Amylase assay is substantially equivalent to the Boehringer Mannheim® α-Amylase/EPS assay (K882225) on the Hitachi® Analyzer for serum, plasma, or urine applications.
These assays yield similar Performance Characteristics.

Similarities to Boehringer Mannheim:

- Both assays are *in vitro* clinical chemistry methods.
- Both assays can be used for the quantitative determination of amylase in serum, plasma, or urine.
- Both assays yield similar clinical results.

Differences to Boehringer Mannheim:

- There is a minor difference between the assay range.

Intended Use:

The amylase assay is used for the quantitation of amylase in human serum, plasma, or urine.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET™ System. The Amylase assay method comparison yielded acceptable correlation with the Boehringer Mannheim α-Amylase/EPS assay on the Hitachi 717 Analyzer for the serum and urine applications. For serum applications, the correlation coefficient = 0.9990, slope = 1.237, and Y-intercept = -1.232 U/L. For urine applications, the correlation coefficient = 0.9963, slope = 1.042, and Y-intercept = 2.102 U/L. Precision studies were conducted using the Amylase assay. Within-run, between-run, and between-day studies were performed using two levels of control material. The total %CV for Level 1/Panel 101 is 1.0% and Level 2/Panel 102 is 1.6% for serum applications, and 1.3% for Level 1/Panel 201, and 1.1% for

Level 2/Panel 202 for urine applications. The Amylase assay is linear up to 3010.3 U/L. The limit of quantititation (sensitivity) for the Amylase assay is 1.8 U/L. These data demonstrate that the performance of the Amylase assay is substantially equivalent to the performance of the Boehringer Mannheim α-Amylase/EPS assay on the Hitachi 717 Analyzer for the serum and urine applications.

Conclusion:

The Amylase assay is substantially equivalent to the Boehringer Mannheim α-Amylase/EPS assay on the Hitachi 717 Analyzer as demonstrated by results obtained in the studies.