March 2, 2018

Phadia AB
℅ Martin Mann
Sr. Regulatory Affairs Manager
Phadia US Inc
4169 Commercial Ave
Portage, Michigan 49002

Re: K173704
Trade/Device Name: ImmunoCAP Tryptase, ImmunoCAP Tryptase Calibrators, ImmunoCAP Tryptase Curve Control, ImmunoCAP Tryptase Conjugate 50, ImmunoCAP Tryptase Calibrator Strip, ImmunoCAP Tryptase Curve Control Strip
Regulation Number: 21 CFR 866.5760
Regulation Name: Tryptase test system
Regulatory Class: Class II
Product Code: OYL
Dated: December 1, 2017
Received: December 4, 2017

Dear Martin Mann:

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,

Kelly Oliner -S

For,
Lea Carrington
Director
Division of Immunology and Hematology 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)*
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Device Name
ImmunoCAP Tryptase

Indications for Use *(Describe)*

ImmunoCAP Tryptase is an in vitro semi-quantitative assay for measurement of tryptase in human serum or plasma (EDTA, lithium heparin or sodium heparin). It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings. ImmunoCAP Tryptase is to be used with the instrument Phadia 100.

ImmunoCAP Tryptase is an in vitro semi-quantitative assay for measurement of tryptase in human serum or plasma (EDTA, lithium heparin or sodium heparin). It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings. ImmunoCAP Tryptase is to be used with the instrument Phadia 250.

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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510(k) Summary

This 510(k) Summary is prepared in accordance with the requirements of 21 CFR Part 807.92.

Premarket Notification 510(k) No: K173704

Date of Summary Preparation: February 7, 2018

Manufacturer:
Phadia AB
Rapsgatan 7P
P.O. Box 6460
751 37 Uppsala, Sweden

US Distributor:
Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002

Company Contact Person:
Martin Mann
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Phadia US Inc.
4169 Commercial Avenue
Portage, MI 49002
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martin.mann@thermofisher.com

Device Name: ImmunoCAP Tryptase

Common Name: In vitro diagnostic test system for semi-quantitative measurement of tryptase

Classification:

Regulation section	21 CFR §866.5760 – Tryptase test system
Classification	Class II
Class II Special Controls Guideline	Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis
Product name	ImmunoCAP Tryptase
Product code	OYL, tryptase assay system

Substantial Equivalence to: ImmunoCAP Tryptase DEN120001 (k103039)

Indications for use statement

ImmunoCAP Tryptase is an in vitro semi-quantitative assay for measurement of tryptase in human serum or plasma (EDTA, lithium heparin or sodium heparin). It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings. ImmunoCAP Tryptase is to be used with the instruments Phadia 100 and Phadia 250.

Device Description

Reagents

ImmunoCAP Tryptase reagents are modular in concept and are available individually in different package sizes dependent on instrument system used.
The reagents needed to perform the ImmunoCAP Tryptase assay are listed below.
ImmunoCAP Tryptase/ImmunoCAP Tryptase Conjugate 50 (10-9525-02/10-9522-02)
ImmunoCAP Tryptase Calibrators/ImmunoCAP Tryptase Calibrator Strip (10-9526-01/10-9523-01)
ImmunoCAP Tryptase Curve Control/ImmunoCAP Tryptase Curve Control Strip (10-9527-01/10-9524-01)
ImmunoCAP Tryptase Anti-Tryptase (14-4518-01), ImmunoCAP Tryptase Control (10-9370-01)

Instrument System

Phadia 100 and Phadia 250 instruments with associated software process all steps of the assay and calculate results automatically after the assay is completed.

Test Principle, ImmunoCAP Tryptase

Anti-tryptase, covalently coupled to ImmunoCAP, reacts with the tryptase in the patient sample. After washing, enzyme labeled antibodies against tryptase are added to form a complex. After incubation, unbound enzyme-anti-tryptase is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more tryptase is present in the sample. To evaluate the test results, the responses of the patient samples are transformed into concentrations with the use of a calibration curve.

Reason for Submission

This submission comprises changes in product raw material made to assay reagents ImmunoCAP Tryptase Conjugate and ImmunoCAP Tryptase Calibrators. The changes do not affect the Intended use or the Indications for use statements.

Performance Characteristics

The updated ImmunoCAP Tryptase was compared with the currently cleared ImmunoCAP Tryptase with the use of samples with and without clinical documentation, as well as samples from healthy individuals. The analytical performance characteristics of the updated ImmunoCAP Tryptase were verified through studies of precision, lot-to-lot reproducibility, linearity, limit of detection, hook, analytical specificity, interference of HAMA, recovery and sample matrix.

The clinical performance was verified through studies performed at two sites, including in total 138 patients with a suspicion of systemic mastocytosis. The results showed that the clinical performance of ImmunoCAP Tryptase has not changed when used as an aid in the routine clinical diagnosis of systemic mastocytosis according to WHO criteria.

Conclusion
The analytical and clinical data included in this 510(k) submission support that the updated ImmunoCAP Tryptase is substantially equivalent to the currently cleared product.