Allergy & Applicator Depot, LLC
% Marc Sanchez
Contract In-House Counsel and Consultants, LLC (FDA Atty)
53516 Bickett Drive
Chapel Hill, North Carolina 27517

November 1, 2024

Re: K182582
Trade/Device Name: Oryum and Ovem Epidermal Skin Prick Test Applicator
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: SCL

Dear Marc Sanchez:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 10, 2019. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code SCL.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact David Wolloscheck, OHT3: Office of GastroRenal, OB-Gyn, General Hospital and Urology Devices, 301-796-1480, David.Wolloscheck@fda.hhs.gov.

Sincerely,

David Wolloscheck -S

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, OB-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 10, 2019

Allergy & Applicator Depot, LLC
% Marc Sanchez
Contract In-House Counsel and Consultants, LLC (FDA Atty)
53516 Bickett Drive
Chapel Hill, North Carolina 27517

Re: K182582
Trade/Device Name: Oryum and Ovem Epidermal Skin Prick Test Applicator
Regulatory Class: Unclassified
Product Code: LDH
Dated: March 6, 2019
Received: March 8, 2019

Dear Marc Sanchez:

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); 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,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)* K182582

Device Name
Oryum and Ovem Epidermal Skin Prick Test Applicator

Indications for Use *(Describe)*
Oryum and Ovem Epidermal Skin Prick Test Applicator is used for the percutaneous administration of diagnostic allergenic extracts.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K182582

510(K) Summary

The following information is provided as required by 21 CFR 807.92 for the Oryum and Ovem Epidermal Skin Prick Test Applicator 510(k) premarket notification.

Sponsor: Allergy & Applicator Depot, LLC
5018 Expressway Dr. S.
Suite LL5
Ronkonkoma, NY 11779
Establishment Registration: t/b/d

Manufacturer: Yılmaz Medikal Mustafa Nazlier
Budak Mah. Hasirci Sami Bey Cad. No: 12
Sehitkamil, Gaziantep, TURKEY
Ph.: +90 342 321 74 77
E-mail: info@yilmazmedikal.com
Establishment Registration: t/b/d

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC
(d/b/a FDA Atty)
1717 Pennsylvania Ave. Suite 1025
Washington, D.C. 20006
Ph: 202.765.4491
E-mail: msanchez@fdaatty.com

Date of Submission: August 23, 2018

Proprietary Name: Oryum and Ovem Epidermal Skin Prick Test Applicator

Common Name: System, Delivery, Allergen And Vaccine

Regulation Number: Pre-Amendment

Regulatory Class: Unclassified

Product Code: LDH

Predicate Device(s): Multi-Test II (K961918)

Device Description: Oryum and Ovem Epidermal Skin Prick Test Applicator is a sterile, disposable, multiple test head applicator used to administer skin test substances to the surface of the skin.

The Oryum and Ovem Epidermal Skin Prick Test Applicator are used for the conventional percutaneous application of substance directly onto the surface of the skin of diagnostic allergen extracts for performing skin tests for hypersensitivity reactions in individuals suspected of having allergies.

The Oryum and Ovem Epidermal Skin Prick Test Applicator is offered in several configurations with 1 to 12 test heads arranged in an asymmetrical design

Each of the test heads have a "leg." At the tip of each leg is an array of protruding test points (tines). The tines utilize capillary action to hold the allergenic material for percutaneous delivery when the applicator is applied to the skin. This is an industry wide standard design.

The test heads are designed to fit into the matching asymmetrical well design of a dipwell tray.

The applicator loads the allergen from each well in the tray on to each test head.
When properly applied to the skin, the applicator will leave visible indentations in the patient's skin corresponding to the test heads of each applicator. The applicator is not intended to pierce the skin.

Intended Use:

Oryum and Ovem Epidermal Skin Prick Test Applicator is used for the percutaneous administration of diagnostic allergenic extracts.

Summary of Non-Clinical Testing
Oryum and Ovem Epidermal Skin Prick Test Applicator has completed non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of the biocompatibility, sterility and performance, which are demonstrated in the table below.

Table 1
Summary of Non-Clinical Performance testing

Biocompatibility	ISO10993-5:2009	In Vitro Cytotoxity Test
	ISO10993-10:2010	Skin Sensitization Test
	ISO10993-10:2010	Skin Irritation Test
	ISO10993-11:2017	Acute systemic toxicity

Sterility	ISO11737-2:2009; ISO 11737-2:1998 Sterilization of Medical Devices	Sterilization of Medical Devices
Shelf-Life Validation	ISO 11737-2:2009	Sterilization of Medical Devices
Performance Testing of Shipping Containers and Systems	ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
Performance comparison with predicate device	Internal method	Comparison of ability to collect sufficient allergen extract from dipwell and deliver to the patient

Summary of Technological Similarities/Differences:

The Oryum and Ovem Epidermal Skin Prick Test Applicator and the predicate are both acrylic plastic model applicators use to load allergenic extracts on the points of the applicator and apply to the skin. They share the same intended use and near identical design. Any differences in technology are minor and do not raise new questions of safety or efficacy.

Table 2
Technological Characteristics

Parameter/application	Oryum and Ovem Epidermal	Multi-Test II (K961918)
Product code	LDH	LDH
Indications for use	Percutaneous administration of diagnostic allergenic extracts.	Percutaneous administration of diagnostic allergenic extracts.
Applicator for Allergenic Extracts	YES	YES
Acrylic Polymer Construction	YES	YES
SAL	10^{-6}	10^{-6}
Sterilization Method	Etyhlene Oxide (applicator); AAMI Guidelines	Etyhlene Oxide (applicator); Gamma Radiation (tray with lid); AAMI Guidelines
Use Area	Skin Surface	Skin Surface
Prick Size	1.2-1.6mm	2.0mm
Lancet Intervals	2.0-2.5cm	2.0-2.4cm
Packaging Method	Sterilization Pouch	Sterilization Pouch
Packaging Materials	PET Plastic	PET Plastic
Shelf Life	3 years	3 years

Conclusion

Therefore, taking into consideration Table 1 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the Oryum and Ovem Epidermal Skin Prick Test Applicator raises no different questions of safety or effectiveness and has been found to be substantially equivalent to the predicate devices.