January 30, 2026

Asistan Medikal
℅ Lee Strong
Regulatory Consultant
510K FDA Inc.
156 E Granada Blvd
Ormond Beach, Florida 32176

Re: K250983
Trade/Device Name: Medblue Skin Prick Test Applicator (AS103, AS108, AS109, AS110, AS111, AS113, AS132, AS134, AS146, AS148, AS160, AS162, AS170, AS172)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: SCL
Dated: January 30, 2026
Received: January 30, 2026

Dear Lee Strong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KYRAN R. GIBSON -S

For

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250983

Device Name
Medblue Skin Prick Test Applicator (AS103, AS108, AS109, AS110, AS111, AS113, AS132, AS134, AS146, AS148, AS160, AS162, AS170, AS172)

Indications for Use *(Describe)*
Used for 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.

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510k FDA Consulting

Medical Device Clearances

156 East Granada Blvd. Ormond Beach, FL 32176 386-506-8711

K250983 510(k) Summary

Applicant

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Consultant/Contact

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Secondary Contact: Claude Berthoin (claude@510kfda.com)
Date Prepared: January 30, 2026

Device Classification

Trade name: Medblue Skin Prick Test Applicator (AS103, AS108, AS109, AS110, AS111, AS113, AS132, AS134, AS146, AS148, AS160, AS162, AS170, AS172)
Common name: Allergen And Vaccine Delivery Needles
Manufacturer: Asistan Medikal, (Gaziantep, Turkey)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: SCL
Predicate Device: Oryum and Ovem Epidermal Deri Skin Prick Test Applicator (K182582)

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) number:	K182582
Clearance date:	April 10, 2019
Trade name:	Oryum and Ovem Epidermal Deri Skin Prick Test Applicator
Common name:	Allergen And Vaccine Delivery Needles
Manufacturer:	Allergy & Applicator Depot, LLC (Chapel Hill, NC, USA)
Regulatory Class:	Class II
Regulation Number:	21 CFR 880.5570
Product Code:	SCL

Intended Use / Indications for Use

Used for percutaneous administration of diagnostic allergenic extracts.

Device Description

The Medblue Skin Prick Test Applicator is a sterile, single use disposable, multiple test head applicator used to administer skin test substances to the surface of the skin.

The Medblue Skin Prick Test Applicator is 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 Medblue Skin Prick Test Applicator is offered in several configurations with 1, 8, 10 or 12 test heads made of medical grade acrylic (ps158N) material arranged in a symmetrical design.

Model AS 113 features a metal tip made of 301 stainless steel. All other models have acrylic tips.

Each of the test heads have a “leg”. At the tip of each leg is an array of protruding test points (tines). Each leg has 1, 6, or 9 tines. The tines utilize capillary action to hold the allergenic material for percutaneous delivery when the applicator is applied to the skin. Each leg has a stopper to prevent going deeper than the epidermis thickness.

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 onto 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.

The Medblue Skin Prick Test Applicator has the following models:

Model	Product
AS103	**MEDBLUE ONE FINGER SKIN PRICK TEST APPLICATOR1 (LANCET)**
AS108	**MEDBLUE SKIN PRICK TEST APPLICATOR 8 PLASTİC TIP SINGLE NEEDLE**
AS109	**MEDBLUE SKIN PRICK TEST APPLICATOR 10 PLASTİC TIP SINGLE NEEDLE**
AS110	**MEDBLUE SKIN PRICK TEST APPLICATOR 12 PLASTİC TIP SINGLE NEEDLE**
AS111	**MEDBLUE ONE SKIN PRICK TEST APPLICATOR 1 PİNLİ (LANCET)**
AS113	**MEDBLUE SKIN PRICK TEST APPLICATOR 10 METAL TIP SINGLE NEEDLE**
AS132	**MEDBLUE SKIN PRICK TEST APPLICATOR 8 SIX NEEDLE**
AS134	**MEDBLUE SKIN PRICK TEST APPLICATOR 8 NİNE NEEDLE**
AS146	**MEDBLUE SKIN PRICK TEST APPLICATOR 10 SIX NEEDLE**
AS148	**MEDBLUE SKIN PRICK TEST APPLICATOR 10 NİNE NEEDLE**
AS160	**MEDBLUE SKIN PRICK TEST APPLICATOR 12 SIX NEEDLE**
AS162	**MEDBLUE SKIN PRICK TEST APPLICATOR 12 NİNE NEEDLE**
AS170	**MEDBLUE SKIN PRICK TEST APPLICATOR 8 SINGLE NEEDLE PEDIATRIC**
AS172	**MEDBLUE SKIN PRICK TEST APPLICATOR 10 SINGLE NEEDLE PEDIATRIC**

Packaging

Medblue Skin Prick Test Applicator is packaged in a polyethylene container with Tyvek paper heat-welded to top edge.

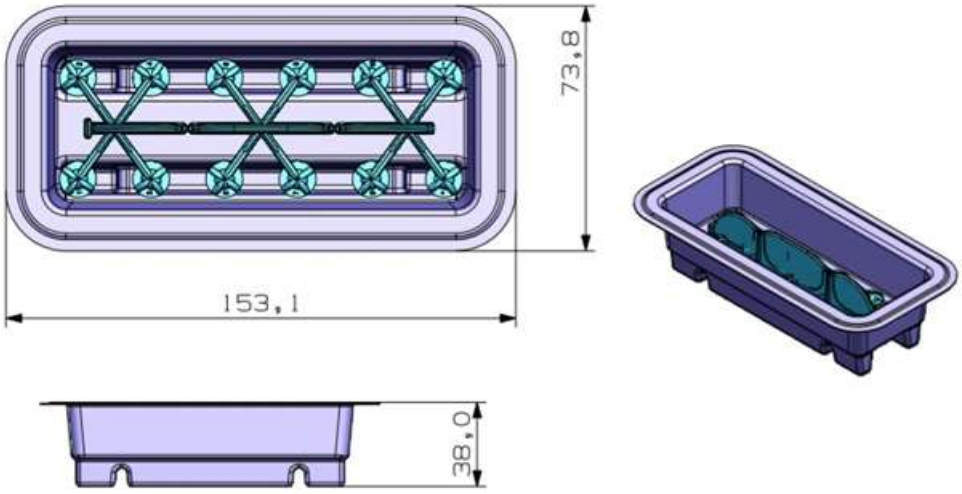
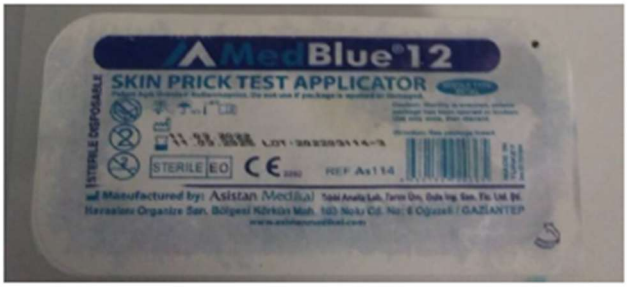


Figure 1 - Diagrams of device in polyethylene container



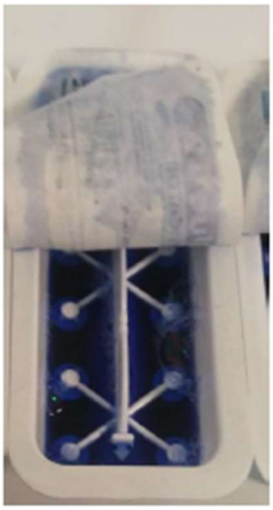


Figure 2 - Photos of Tyvek label on container

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

	Oryum and Ovem Epidermal Skin Prick Test Applicator (K182582)	Medblue Skin Prick Test Applicator (Subject Device)	Comparison
Product code	SCL	SCL	Same
Indications for use	Percutaneous administration of diagnostic allergenic extracts.	Percutaneous administration of diagnostic allergenic extracts.	Same
Applicator for Allergenic Extracts	YES	YES	Same
Acrylic Polymer Construction	YES	YES	Same
SAL	10^{-6}	10^{-6}	Same
Sterilization Method	Ethylene Oxide (applicator); AAMI Guidelines	Ethylene Oxide (applicator); AAMI Guidelines	Same
Use Area	Skin Surface	Skin Surface	Same
Prick Size	1.2-1.6mm	1.10-1.5mm	Different: Subject device has a smaller prick size
Lancet Intervals	2.0-2.5cm	20.0-30.5mm	Different: Subject device has a larger lancet interval
Packaging Method	Sterilization Pouch	Sterilization Pouch	Same

	Oryum and Ovem Epidermal Skin Prick Test Applicator (K182582)	Medblue Skin Prick Test Applicator (Subject Device)	Comparison
Packaging Materials	PET Plastic	PET Plastic + Tyvek Paper	Different: Subject device uses PET with the additional use of Tyvek paper
Shelf Life	3 years	3 years	Same

Differences between the subject and predicate devices are seen in the shape, size, design of the device and those are in cm and mm measurements of slight difference. The differences of the device do not raise new or different question of safety and effectiveness when compared to the predicate device. A combination of bench and clinical performance testing were performed to support that the differences in technological characteristics were adequately verified and validated.

Clinical Performance Evaluation

Clinical testing of the Medblue Skin Test Applicator and Oryum and Ovem Epidermal Deri Skin Prick Test Applicator (predicate device K182582) was conducted to establish equivalence to the predicate device through side-by-side testing.

Mean wheal diameters were compared showing no statistically significant differences in effectiveness of allergen delivery between subject and predicate devices. Pain assessment, using the Wong-Baker FACES Pain Rating Scale, showed no significant differences between Medblue and Oryum & Ovem applicators. It was observed that both devices were able to administer the allergenic extract percutaneously to elicit comparable reactions.

Biocompatibility

The device was tested for conformance to the following standards:

ISO lO993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO lO993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008/Amd 1:2019 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals Amendment 1: Applicability of allowable limits for neonates and infants
ISO lO993-10:2010 Tests for irritation and skin sensitization
ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity

Sterilization

The device conforms to the following standards for Ethylene Oxide Sterilization:

ISO 11135-1:2014 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11737-1:2018/AMD 1:2021 Sterilization of health care products— Microbiological methods Part 1: Determination of a population of microorganisms on products

ISO 11737-2:2019 Sterilization of health care products – Microbiological Methods Part 2: Tests of Sterility Performed in the definition, validation and maintenance of a sterilization process

Package integrity validation was confirmed after shelf-life and simulated shipping.

Conclusion

In conclusion, the comparison of intended use and technological characteristics, combined with the subject device testing, supports that the subject Medblue Skin Prick Test Applicator raises no new or different questions of safety or effectiveness, and is substantially equivalent to the predicate Oryum and Ovem Epidermal Deri Skin Prick Test Applicator.