



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

September 29, 2015

West Pharmaceutical Services Inc.  
Mr. Jeffrey Ravel  
Director, Regulatory Affairs  
530 Herman O. West Drive  
Exton, Pennsylvania 19341

Re: K151777  
Trade/Device Name: Intradermal Adapter  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: FMF  
Dated: June 30, 2015  
Received: July 1, 2015

Dear Mr. Ravel:

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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
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for Erin I. Keith, M.S.

Director  
Division of Anesthesiology,  
General Hospital, Respiratory, Infection  
Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151777

Device Name

Intradermal Adapter

Indications for Use (Describe)

The Intradermal Adapter is an accessory to a 1ml, ½ inch fixed-needle allergy syringe indicated for use on patients ranging from children 2 year to adults, as a guide for performing intradermal injections.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.\***

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## 510(k) Summary

**Device:** Intradermal Adapter

**Company Name:**

West Pharmaceutical Services, Inc.  
530 Herman O. West Drive  
Extron, PA 19341

**Contact Person:**

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Director of Regulatory Affairs  
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**Preparation date:** 29 September 2015

**Classification:**

<b>Classification name:</b>	Syringe, Piston (Accessory)
<b>Trade name:</b>	Intradermal Adapter
<b>Common/usual name:</b>	Intradermal Adapter (ID Adapter)
<b>Product Code:</b>	FMF
<b>Regulation No.:</b>	21 CFR 880.5860
<b>Class:</b>	II
<b>Panel Identification:</b>	General Hospital

**Predicate Devices:** K123588 Intradermal Adapter

**Device Description:**

The Intradermal Adapter consists of a single injection molded part manufactured from a medical grade polycarbonate. The Intradermal Adapter is a piston syringe accessory which is designed

**West Intradermal Adapter**

**Traditional 510(k)**  
*West Pharmaceutical Services, Inc.*

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for use with 1mL allergy syringes with ½ inch (27g), (28g), (29g) needles, which are commonly used for intradermal injections given with a traditional Mantoux technique.

The Intradermal Adapter has been designed to snap fit on to the end of the syringe forming an injection guide to control the depth and angle of needle insertion exposing only the minimal needle length required to perform a successful intradermal injection. The Intradermal Adapter is provided sterile in an individually packaged configuration.

**Indication for Use:**

The Intradermal Adapter is an accessory to a 1ml, ½ inch fixed-needle allergy syringe indicated for use on patients ranging from children 2 years old to adults, as a guide for performing intradermal injections.

**Technological Characteristics and Substantial Equivalence:**

The Intradermal Adapter utilized as an accessory to the piston syringe has the same purpose and principle of operation as the predicate device with respect to performing an injection below the surface of the skin including intradermally and is therefore substantially equivalent to the cleared device referenced: K123588 (West Pharmaceutical Services - Intradermal Adapter).

<b>Areas for comparison</b>	<b>Claimed Substantially Equivalent Product West Intradermal Adapter K123588</b>	<b>Proposed Device Intradermal Adapter Subject 510(k)</b>	<b>Comparison</b>
<b>Indication for Use</b>	The Intradermal Adapter is an accessory to a 1 ml, ½ inch fixed- needle allergy syringe indicated for use as a guide for performing intradermal injections	The Intradermal Adapter is an accessory to a 1ml, ½ inch fixed- needle allergy syringe indicated for use on patients ranging from infants to adults, as a guide for performing intradermal injections.	Modified Only patient population has changed. The form and function of the proposed device has not been modified from the predicate device in order to incorporate an expanded patient population
<b>Sterilization Method</b>	Sterile Ethylene Oxide SAL 10 <sup>-6</sup>	Sterile Ethylene Oxide SAL 10 <sup>-6</sup>	Identical
<b>Single use</b>	Yes	Yes	Identical
<b>Control of Injection Depth</b>	Design of Intradermal Adapter limits the exposed needle of the compatible piston	Design of Intradermal Adapter limits the exposed needle of the compatible piston	Identical

## West Intradermal Adapter

**Traditional 510(k)**  
West Pharmaceutical Services, Inc.

Areas for comparison	Claimed Substantially Equivalent Product West Intradermal Adapter K123588	Proposed Device Intradermal Adapter Subject 510(k)	Comparison
	syringe to control depth and angle of injection	syringe to control depth and angle of injection	
<b>Material</b>	Polycarbonate	Polycarbonate	Identical
<b>Type of Injection and needle gauge size</b>	Intradermal Compatible with 27-29 gauge needles	Intradermal Compatible with 27-29 gauge needles	Identical
<b>Delivery form and dosing system</b>	Manual, using syringe with Intradermal Adapter (Utilizes standard syringe-vial dosing system)	Manual, using syringe with Intradermal Adapter (Utilizes standard syringe vial dosing system)	Identical
<b>Compatible Syringe type</b>	Adapter fits to piston syringe barrel - 1 ml disposable, ½ inch, 27g to 29g fixed needle syringe	Adapter fits to piston syringe barrel - 1 ml disposable, ½ inch, 27g to 29g fixed needle syringe	Identical
<b>Delivery form and dosing system</b>	Manual, using syringe with Intradermal Adapter (Utilizes standard syringe-vial dosing system)	Manual, using syringe with Intradermal Adapter (Utilizes standard syringe vial dosing system)	Identical
<b>Syringe supply</b>	Separate from the device	Separate from the device	Identical

**Performance Testing:**

Performance testing including bench, animal, and simulated use was leveraged from the predicate K123588 submission. The data collected throughout the course of these studies included bevel up and bevel down configurations using 27g to 29g needles as compared to the Mantoux method. Information gathered from medical literature obtained through peer reviewed journal articles was obtained and used to support expanding the indications for use as the injection depth is properly controlled by the geometry of the ID Adapter indicating no compromise to the intended depth of penetration for the expanded patient population. Results of performance testing demonstrated that the Intradermal Adapter, when used as an accessory to the piston syringe, can be indicated for administering intradermal injections to the indicated patient population.

The peer reviewed studies presented in this submission confirm through the acquisition of data from 485 pediatric patients, that the controlled design of the ID Adapter prevents an injection

depth to greater than 0.75mm which is well within the epidermis + dermis layer necessary for successful intradermal injection in a pediatric patient age group. Based on the clinical journal data presented in this submission in conjunction with the visual references of injection application and physical limitations of the device, the ID Adapter is acceptable for use in expanded intended use applications for a wider patient age range including pediatric patients over the age of 2 years.

**Conclusion:**

Comparative analysis of the technological characteristics between the proposed and predicate device and results of verification testing performed demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.