DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 2, 2017

West Pharmaceutical Services, Inc.
Ms. Ana Ladino
Director of Regulatory Affairs
530 Herman O. West Drive
Exton, Pennsylvania 19341-1147

Re: K163511
Trade/Device Name: NovaGuard SA Pro Safety System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 14, 2016
Received: December 15, 2016

Dear Ms. Ladino:

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,

Tina Kiang -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K163511

Device Name
NovaGuard SA Pro Safety System

Indications for Use *(Describe)*

Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

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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"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."

510(K) SUMMARY : K163511

Device: **NovaGuard SA Pro Safety System**

Company Name:

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Preparation date: January 31, 2017

Classification:

Classification Name: Piston Syringe
Trade Name: NovaGuard SA Safety System
Common/Usual Name: Anti Stick Syringe
Product Code: MEG
Regulation No.: 21 CFR 880.5860
Class: II
Panel Identification: General Hospital Panel

Predicate Device:

NovaGuard SA Safety System 510(k) K141464.

Device Description:

The proposed device, NovaGuard SA Pro Safety System, is a non-sterile, single use anti needlestick accessory for pre-filled ISO standard glass syringes that are 1ml long with a max needle length of 5/8". The NovaGuard SA Pro Safety System consist of three components, syringe holder, sleeve and spring. The proposed device will be assembled along with the pre filled syringe by the pharmaceutical company. Upon completion of the injection, the needle is then covered by the sleeve protecting the user from potential sharps needle stick injury. There is a visual, tactile and audible recognition that the device safety feature has activated.

Indications for use:

Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients, from accidental needlesticks. The intended patient population is unrestricted and may include children and adults, and parenteral methods of administration.

Substantial equivalence:

Based on the indications for use, technology, materials of construction and principle of operation the proposed device, NovaGuard SA Pro Safety System, is substantially equivalent to the predicate device, NovaGuard SA Safety System 510(k) K141464.

The following modifications have been made to the predicate device, NovaGuard SA Safety System 510(k) K14146:

- Syringe holder modifications to implement integrated clip features instead of a separate clip component.
- Syringe holder modifications to aid in the molding and assembly process and to smooth the syringe holder fingers profile.

The predicate device, NovaGuard SA Safety System (K141464) includes a separate clip component. The proposed device, NovaGuard SA Pro Safety System includes an integrated clip feature on the syringe holder instead of a separate clip component. This change was implemented to facilitate the pharmaceutical manufacturer assembly process of the proposed device, NovaGuard SA Pro Safety System, with their prefilled syringe. This device modification eliminates the need to assemble a clip component as a separate operation.

Areas for Comparison	Predicate Device: NovaGuard SA Safety System (K141464)	Proposed Device: NovaGuard SA Pro Safety System	Comparison
Indications for Use	Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients from accidental needle sticks. The intended patient population is unrestricted and may include children and adults and parenteral methods of administration.	Single use device that is indicated for use as an accessory with pre-filled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications and individuals that assist self-injecting patients from accidental needle sticks. The intended patient population is unrestricted and may include children and adults and parenteral methods of administration.	Identical
Use	Single Use	Single Use	Identical
Prescription Use	Yes	Yes	Identical
Contraindication	None	None	Identical
Components	Syringe holder, sleeve, spring and clip	Syringe holder, sleeve and spring	Modified Integrated clip replaces the clip component
Compatible Syringes	Pre-filled ISO Standard glass syringes	Pre-filled ISO Standard glass syringes	Identical
Syringe size	1mL Long	1mL Long	Identical
Needle Length	Max 5/8” length	Max 5/8” length	Identical
Needle shield requirement	Rigid	Rigid	Identical
Syringe holder material of	Polycarbonate	Polycarbonate	Identical

Areas for Comparison	Predicate Device: NovaGuard SA Safety System (K141464)	Proposed Device: NovaGuard SA Pro Safety System	Comparison
construction			
Sleeve material of construction	Polycarbonate	Polycarbonate	Identical
Spring material of construction	Stainless Steel	Stainless Steel	Identical
Clip material of construction	Polycarbonate	N/A	Modified The NovaGuard SA Pro Safety System does not have a separate clip component
Biocompatible	Yes Per ISO 10993-1	Yes Per ISO 10993-1	Identical
Sterilization	Non- sterile	Non- sterile	Identical

Performance Testing:

Based on the verification and validation activities, along with the risk assessment evaluation, it was determined that the following tests needed to be performed on the proposed device, NovaGuard SA Pro Safety System.

- Syringe assembly force
- Pre-activation disassembly force (force applied to RNS)
- Pre-Activation Disassembly Force Test (force applied to cannula)
- Clip impact test (Integrated clip feature test)
- Drop Test - Post-activation with PFS
- Drop Test – Pre-activation with PFS
- Activation Security
- RNS replacement

All testing met the required acceptance criteria.

Performance Testing Summary	
Test Name	**Testing Standard**
Syringe assembly force	Tested to internal performance standards
Pre-activation disassembly force (force applied to RNS)	Tested to internal performance standards
Pre-Activation Disassembly Force Test (force applied to cannula)	Tested to internal performance standards
Clip impact test (Integrated clip feature test)	Tested to internal performance standards
Drop Test - Post-activation with PFS	Tested to internal performance standards
Drop Test – Pre-activation with PFS	Tested to internal performance standards
Activation Security	Tested to internal performance standards
RNS replacement	Tested to internal performance standards

The bench testing evaluation of the proposed device, NovaGuard SA Pro Safety System, does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device.

Clinical Testing:

The proposed device, NovaGuard SA Pro Safety System, modifications did not affect the device design impacting activation of the safety prevention feature therefore based upon their risk analysis a simulated use study was deemed not necessary.

Conclusion:

Based on the indications for use, technology, materials of construction and principle of operation the proposed device NovaGuard SA Pro Safety System, is substantially equivalent to the predicate device, NovaGuard SA Safety System (K141464).