August 3, 2018

MHC Medical Products, LLC.
℅ Daniel Kamm
Kamm & Associates
8870 Ravello Ct.
Naples, Florida 34114

Re: K163578
Trade/Device Name: EasyTouch™ Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 3, 2018
Received: July 6, 2018

Dear Daniel Kamm:

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, 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)*
K163578

Device Name
EasyTouch™ Safety Pen Needle

Indications for Use *(Describe)*

The EasyTouch™ Safety Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

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.

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510(k) Summary K163578

MHC Medical Products
8695 Seward Rd.
Fairfield, OH 45011
Tel: 877-358-4342
Contact Person: Sean O'Keefe

Date Prepared: August 1, 2018

1. **Identification of the Proposed Device:**
   Trade Name: EasyTouch™ Safety Pen Needle
   Regulation Number: 21 CFR 880.5570
   Regulation Name: Hypodermic Single Lumen Needle
   Regulatory Class: Class II
   Product Code: FMI

2. **Identification of the Predicate Device:**
   BD Autoshield™ Pen Needle, K060007.
   Regulation Number: 21 CFR 880.5570
   Regulation Name: Hypodermic Single Lumen Needle
   Regulatory Class: Class II
   Product Code: FMI

3. **Description of Device**: EasyTouch™ Safety Pen Needle is designed to be used with pen injectors for subcutaneous injections of a desired dose of drugs approved for delivery using a pen needle. The EasyTouch™ Safety Pen Needle is sterile (Ethylene Oxide sterilization procedure), and non-pyrogenic. It is a disposable, single use device. Additionally, the EasyTouch™ Safety Pen Needle is designed to reduce the occurrence of accidental needle sticks by providing a sheath that locks of the needle after use. Prior to injection, the end user will attach the EasyTouch™ Safety Pen Needle to an injector pen. The protective sheath will hide the needle from the user prior to use. Upon application of the needle to the skin, the sheath will retract to allow for the needle to enter the body. After the injection is complete, and the needle is removed from the skin, the protective sheath will automatically extend over the needle and lock into place. The EasyTouch™ Safety Pen Needle should be removed from the pen and discarded properly.

4. **Intended Use/Indications for Use:** The EasyTouch™ Safety Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

5. **Technical Characteristics:** EasyTouch™ Safety Pen Needles and the predicate devices have identical technological characteristics and perform the same way as common pen needles. The EasyTouch™ Safety Pen Needle and the predicate device both include safety features that are identical in function and performance. A detailed comparison table follows:

Comparison Table

	BD Autoshield™ Pen Needle, K060007	EasyTouch™ Safety Pen Needle
Indications for Use	The BD AutoShield™ Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	The EasyTouch™ Safety Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection. **SAME.**
USE	OTC	**SAME**
Principle of operation	Serves as a single use pen needle. The device is removed from its packaging and screwed into a pen injector device. The patient then injects the medicine by first setting the dose on the pen, and then inserting the needle into the skin and then pressing the button on the pen. After the injection the needle automatically retracts into a shielded housing, thus preventing an accidental needle stick.	**SAME**
Interface with pen injector (e.g. luer taper or others),	Employs standardized dimensions and luer taper per ISO 11608, Needle-based injection systems for medical use — Requirements and test methods —The dimensions of the attachment part of the needle shall be such that the needle fits and functions with pen injectors which are in accordance with ISO 11608-1. Unscrewing torque of the needle: 0.06~0.08 N.m. The standard 6% luer taper is employed to help ensure a leak free connection to the syringe or pen assembly.	**SAME**
Material information: Hub, Hub protector, Safety feature Needle	Hub: Polypropylene Hub Protector: Polypropylene Safety Feature: Stainless steel spring Needle: 304 Stainless steel needle with silicone lubricant	Hub: Polypropylene Hub Protector: Polypropylene Safety Feature: Stainless steel spring Needle: 304 Stainless steel needle with silicone lubricant **SAME**
Sizes/Lengths	29G, 30G, and 31G 5 mm, 8 mm, 12.7 mm lengths	29G: 3/16" (5mm) and 5/16" (8mm) (29G only). This is a subset of the predicate.
Sterilization	SAL: 10^{-6} Gamma Sterilized	SAL: 10^{-6} **SAME** Ethylene Oxide **EQUIVALENT** **See discussion below.**
Shelf life	5 Years	5 Years **SAME**
Single use	YES	YES **SAME**
Biocompatibility	Complies with ISO10993	Complies with ISO10993

	BD Autoshield™ Pen Needle, K060007	EasyTouch™ Safety Pen Needle
	series standards, (presumed, not stated in 510(k) summary)	series standards, and the following tests are performed, • Cytotoxicity: No cytotoxicity • Skin Irritation: No evidence of skin irritation • Skin Sensitization: No evidence of sensitization • Acute Systemic Toxicity: No systemic toxicity • Hemolysis: No evidence of hemolysis **SAME**
Photo		 SIMILARITY IS OBVIOUS

6. Non-clinical testing: Bench Tests were performed. Bench Testing included:

a. Performance of a Risk Analysis to guide the bench testing regimens.

b. Biocompatibility per the ISO10993 series of biocompatibility tests:
In- Vitro Cytotoxicity report, ISO 10993-5
Skin Sensitization test report ISO-10993-10
Intracutaneous study , ISO-10993-10
Systemic Toxicity test report, ISO-10993-11
Pyrogen test report , ISO-10993-11
All tests passed.

c. Mechanical testing: To establish proper functioning of the safety feature, testing was performed to evaluate the function of the of the safety feature in a simulated clinical environment utilizing both professional health care workers and non-clinician pen users using gloved hands. Reference: FDA Guidance Document: Guidance for Industry and FDA Staff, Medical Devices with Sharps Injury Prevention Features Document Issued on: August 9, 2005

d. Pen injector compatibility testing was performed to show that the pen needle works properly with multiple brands of pen injectors. Validation basis ISO11608-1 and ISO11608-2

e. Sterility testing including EO residues. A sterility assurance level of 10^{-6} has been demonstrated. We use Ethylene oxide sterilization whereas the predicate device uses gamma sterilization. The SAL levels for both methods are the same.

f. Packaging and shelf life testing: Accelerated packaging testing was performed to assure a 5 year shelf life: Packaging integrity, packaging permeability, compression resistance, resistance to bacteria.

g. Testing was performed to assure compliance with ISO 7864, Sterile hypodermic needles for single use -- Requirements and test methods.

h. Testing was performed to assure compliance with ISO 9626, Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods

7. **Clinical testing:** Clinical testing was not required (per FDA guidance) to establish substantial equivalence. However SIMULATED CLINICAL TESTING was performed to meet the requirements of the FDA Guidance on Sharps Injury Prevention (2005) (see above)

8. **Conclusion: Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to legally marketed predicate device BD Autoshield™ Pen Needle, K060007.**