DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 19, 2016

Diabetic Supply of Suncoast, Inc.
c/o Matt Hedlund
510k Consultant
3924 NE 157th Place
Lake Forest Park, Washington 98155

Re: K160199
Trade/Device Name: Advocate Insulin Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: September 21, 2016
Received: September 22, 2016

Dear Matt Hedlund:

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 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)*

K160199

Device Name
Advocate Insulin Pen Needles

Indications for Use *(Describe)*
These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.

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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**510(k) Summary for K160199**

Diabetic Supply of Suncoast, Inc.
PO Box 2102
Vega Alta, PR 00692
1-866-373-2824
Contact: Victoria Thuss
Date Prepared: October 11, 2016

1. Subject Device
   Trade Name: Advocate Insulin Pen Needles
   Common Name: Pen Needle
   Regulation Number: 21 CFR 880.5570
   Regulation Name: Hypodermic single lumen needle
   Regulatory Class: Class II
   Product Code: FMI

2. Predicate Device
   Trade Name: Comfort EZ Pen Needle
   510(k) Number: K121632
   Common Name: Pen Needle
   Regulation Number: 21 CFR 880.5570
   Regulation Name: Hypodermic single lumen needle
   Regulatory Class: Class II
   Product Code: FMI

3. Description of Device: The Advocate Insulin Pen Needle consists of a polypropylene 'outer cap' enclosure. This polypropylene cap contains an opening at one end to allow the needle or cannula to exit. The other end of the outer cap is the 'hub' that can be connected to various pens. Contained within the outer cap is the cannula assembly made up of the stainless steel cannula that is contained within an 'inner cap' polypropylene shell that is located on top of the hub. Medical grade blister paper covers and seals the hub. The Advocate Insulin Pen Needles when sealed with the blister paper are EO sterilized and provide a sterile fluid path during use. The Advocate Insulin Pen Needles when connected to the pen injector, is intended for subcutaneous injection of insulin.

4. Indications for Use: *These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes*. This is the same indication for use statement as the statement for the predicate device, K121632.

5. Technological characteristics: The following is a comparison of the technological characteristics of the subject device with the predicate device:

| Technological Characteristic | Subject Device<br>Advocate Insulin Pen Needle | Predicate Device<br>Comfort EZ Pen Needle - K121632 |
|---|---|---|
| Size | 31G 5 mm; 31G 6 mm;<br>31G 8 mm; 32G 4 mm;<br>33 G 4 mm; 29G 12mm | 31 G 5 mm; 31 G 6 mm;<br>31 G 8 mm; 32 G 4 mm;<br>32 G 5 mm; 32 G 6 mm |
| Design | Outer Cap; Inner Cap; Cannula; Hub; Paper Seal | Outer Cap; Inner Cap; Cannula; Hub; Paper Seal |
| Material | Polypropylene; Stainless Steel; Dialyzing Paper; Glue; Silicone Oil | Polypropylene; Stainless Steel; Dialyzing Paper; Glue; Silicone Oil |
| Sterilization | EO Sterilization<br><br>SAL of $10^{-6}$ | EO Sterilization<br><br>SAL of $10^{-6}$ |
| Labeling | Primary Packaging Label-Size; EO Sterile; Use By Date; Lot; Single Use; Manufacturer Information;<br>Warnings; Enclosed Package Insert. | Primary Packaging Label-Size; EO Sterile; Use By Date; Lot; Single Use; Manufacturer Information;<br>Warnings. |
| Performance Testing | Biocompatibility<br>Pen Injector (NIS) Compatibility<br>Mechanical Testing<br>Sterility Validation<br>EO Residue<br>Shelf Life Testing | Biocompatibility<br>Pen Injector (NIS)Compatibility<br>Mechanical Testing<br>Sterility Validation<br>EO Residue<br>Shelf Life Testing |

Conclusion: The technological characteristics of the Advocate Insulin Pen Needles are the same as the Predicate Device. The differences of certain pen sizes (33 G 4 mm; 29G 12mm) with the Predicate Device do not raise new questions of safety and/or effectiveness as these two pen sizes have the same intended use, material, design, sterilization, labeling, and performance testing as the Predicate Device.

6. Performance testing: The following table defines the nonclinical performance testing submitted. All pre-determined acceptance criteria were met:

| Performance Test | Normative References/ Description |
|---|---|
| Accelerated Shelf Life | ASTM F 1980-07<br>ISO 11607-1<br>ISO 11608-2<br>ASTM F 1929<br>ASTM F88 |
| EO Sterilization Validation<br><br><br>EO Residual | The validation process used a standard half cycle method to demonstrate the efficacy of the EO sterilization process.<br><br>Sterilant residual limit for limited exposure met of EO≤4mg and ECH ≤9mg. |
| Biocompatibility Testing | Cytotoxicity – ISO 10993-5<br>Sensitization – ISO 10993-10<br>Intracutaneous reactivity – ISO 10993-10<br>Systemic Toxicity - ISO 10993-11<br>Haemocompatibiltiy – ISO 10993-4 |
| Performance Testing | ISO 11608 – 2 Includes mechanical testing and determination of functional compatibility with specific pen injector devices (NIS). |

Conclusion: The performance testing demonstrates that the Advocate Insulin Pen Needles submitted under this 510(k) are substantially equivalent to the Predicate Device.