DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 19, 2017

Certa Dose, Inc.
% James Boiani
Epstein Becker & Green, PC
1227 25th St NW, Suite 700
Washington, District of Columbia 20037

Re: K160589
Trade/Device Name: Certa Dose™ PD Epinephrine 1mg/mL IM/SC Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: PQX
Dated: December 19, 2016
Received: December 21, 2016

Dear James Boiani:

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)*
K160589

Device Name
Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe

Indications for Use *(Describe)*
The Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is intended for healthcare professionals to deliver epinephrine 1 mg/mL via intramuscular or subcutaneous injection for pediatric patients.

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
K160589

I. SPONSOR AND CORRESPONDENT

Sponsor:
Certa Dose, Inc.
573 Race Street
Denver, CO 80206

Submission Correspondent:
James A. Boiani, MS, JD
Epstein Becker & Green, P.C.
1227 25th St., NW
Suite 700
Washington, DC 20037

Date Prepared: January 19, 2016

II. DEVICE

Name of Device: Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe
Classification Name: Piston Syringe, 21 CFR 880.5860
Regulatory Class: II
Product Code: PQX, Epinephrine Syringe

III. PREDICATE DEVICES

Primary: Monoject 3/10mL U-100 Insulin Syringe w/ Attached 29 Gauge x ½" Needle, K991758
Secondary: Terumo® 31G ThinPro Insulin Syringe, K071630
Reference Device: UniTox® Syringe, K123710
Reference Device: BD Flu+ Syringe, K091377

IV. DEVICE DESCRIPTION

The Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is comprised of (A) a 3/10mL Syringe with an attached 29 Gauge x ½ inch Needle, and (B) a plastic overlay which provides barrel markings. The items on the overlay include (1) a zero line, (2) 0.01 mL unit graduation markings, (3) secondary graduation markings at 0, 0.05, 0.10, 0.15, 0.20, 0.25, 0.30 mL, (4) color bars, and (5) the name of the drug for which the syringe is indicated, epinephrine 1 mg/mL.

V. INDICATIONS FOR USE

The Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is intended for healthcare professionals to deliver epinephrine 1 mg/mL via intramuscular or subcutaneous injection for pediatric patients.

VI. SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICES

Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is substantially equivalent to the predicates as it has
(1) the same intended use, and
(2) the same technological characteristics as the predicates, or where it has different technological characteristics, they do not adversely affect the device safety or effectiveness relative to the predicates, and do not raise different questions of safety or effectiveness.

1. The Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe Has the Same Intended Use as the Predicates and Other Piston Syringes

The intended use of the device is identical to the predicates: the delivery of fluid. The indication differs from that of the predicates only with respect to the specific medication for which it is indicated. However, FDA has cleared multiple drug-specific syringes within the piston syringe device classification, as discussed above. Further, the decision-making factors that FDA provides in its guidance for evaluating whether a specific indication[1] falls within a general intended use support the conclusion that the intended use of the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is the same as those of the predicates.

2. The Differences in Technology from the Primary Predicate Do Not Adversely Affect Safety or Effectiveness, or Raise New Questions of Safety or Effectiveness

The Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is identical to the materials, design, and packaging of the primary predicate, except for the differences summarized below:

ATTRIBUTE	Certa Dose™ PD Epinephrine 1mg/mL IM/SC Syringe	Primary Predicate
510(k) Number	**K160586**	**K991758**
a. Drug and Device Compatibility	Epinephrine 1 mg/mL	U-100 Insulin
b. Unit Graduations	0.01 mL	0.5 Units of Insulin (“UI”)
c. Secondary Graduations	0, 0.05, 0.10, 0.15, 0.20, 0.25, 0.30 mL	5, 10, 15, 20, 25, 30 UI.
d. Color Zones	Color zones that aid as a confirmatory check on volume to be administered	None
e. Application of Barrel Markings	Applied Using Plastic Overlay	Applied Directly to Barrel

[1] FDA Guidance for Industry: General/Specific Intended Use (1998).

In addition, the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is identical to the Secondary Predicate with respect to the use for pediatric populations, with the following exception:

ATTRIBUTE	Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe	Secondary Predicate
510(k) Number	K160589	K071630
f. Design for Indicated Pediatric Population	Syringe for epinephrine 1 mg/mL with 1/2" 29 Gauge Ultrafine Needle	Syringe for U-100 insulin with 3/8" 31 Gauge Ultrafine Needle

Each of these attributes (a through f) is addressed below.

a. The design of the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is appropriate for delivering epinephrine. The syringe components that come into contract with the drug are standard nonreactive materials used in syringe construction – clarified radiation grade polypropylene (barrel material), synthetic isoprene (plunger tip material), silicone (lubricant), and stainless steel (needle) – and raise no concerns with respect to delivery of liquid medication, such as insulin (with the predicate devices) or epinephrine (with the submitted device), in light of the nature of materials (nonreactive) and indication for use in drug delivery (resulting in virtually no contact time epinephrine). Drug contact studies were also conducted to confirm that short contact times do not adversely impact drug quality.

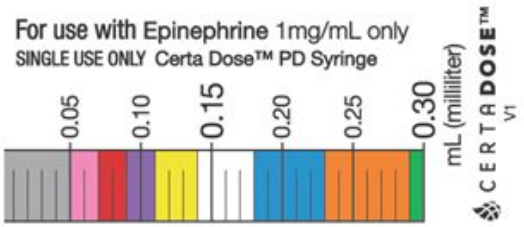
b. Graduation unit markings on drug-specific syringes are chosen based on what resolution of markings would provide the level of specificity commonly required for the drug in question. The 0.01 mL unit graduations markings were chosen to provide the level of specificity that may be commonly required for measuring epinephrine 1 mg/mL volumes. Similar adjustments have been made in the past for other drugs (see predicates and reference devices above).

c. Secondary graduations markings of 0, 0.05, 0.10, 0.15, 0.20, 0.25, 0.30 mL are evenly spaced graduations that are consistent with those observed with the even spacing of the predicate syringes.

d. The color zones (bars of color) on the syringe provide an aid in confirming the drawn volume of fluid. Also, the colors being used correspond to the universal color system pioneered by the Broselow-Luten system which has been widely adopted in the professional use pediatric patient setting for which the syringe is intended. A description of the correlation between colors, weights, and volumes is provided below.

Use the Certa Dose Syringe color zones that align with standard color coding for pediatric weight ranges as a visual aid to help **confirm** if calculated (0.01 mg/kg) and measured volumes (mL) of Epinephrine 1 mg/mL are within the standard dosing recommendations for anaphylaxis in pediatric patients under 30 kg (66 lbs).				
Standard Pediatric Color Coding System for Weight		**Certa Dose™ PD Epinephrine Syringe: Volume and mg Epinephrine**		
Color	Weight Range	Color	Volume Range (mL)	Amt. of Epinephrine (mg)
Grey	3-5 kg	Grey	0.00-0.05	0.00-0.05
Pink	6-7 kg	Pink	0.05-0.07	0.05-0.07
Red	8-9 kg	Red	0.07-0.09	0.07-0.09
Purple	10-11 kg	Purple	0.09-0.11	0.09-0.11
Yellow	12-14 kg	Yellow	0.11-0.14	0.11-0.14
White	15-18 kg	White	0.14-0.18	0.14-0.18
Blue	19-23 kg	Blue	0.18-0.23	0.18-0.23
Orange	24-29 kg	Orange	0.23-0.29	0.23-0.29
Green	30-36 kg	Green	0.29-0.30	0.29-0.30

Certa Dose™ PD Epinephrine Syringe Graduations and Markings



e. The barrel markings are clear, stable (e.g., fade-resistant), and accurately reflect volumes. Specifications regarding application of the markings will ensure that the markings are correctly applied and provide for accuracy. Syringe accuracy testing after sterilization and accelerated aging are used to verify that the markings are applied correctly and remain accurate.

f. The Certa Dose device is mechanically identical to the Monoject Syringe, which has been used by the general population, including children, for several years. The syringe is also similar to the secondary predicate, the Terumo® 31G ThinPro Insulin Syringe with respect to product design, only differing slightly with respect to markings and the use of a slightly larger needle gauge – 29 gauge Ultrafine needle for the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe (and the Primary Predicate) versus 31 gauge needle for the Secondary Predicate – and slightly longer length – 1/2" versus 3/8". Both gauges are considered "ultrafine."

The questions with regard to evaluating the safety and effectiveness of the device design for the indicated patient population require answering the same questions regarding syringe design. In this case, the syringe is specifically designed to deliver epinephrine 1 mg/mL and employs graduation markings and color zones (which are used for pediatric patients) that are appropriate for pediatric patient application.

Based on the foregoing, the differences with respect to design do not raise new questions of safety or effectiveness, and the information above supports that the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe is substantially equivalent to its predicates.

VII. PERFORMANCE TESTING

The following performance testing was conducted to support the substantial equivalence of the subject device:

- Drug-device compatibility studies were conducted to confirm that short contact times do not adversely impact drug quality.
- Syringe accuracy testing to verify that the markings are applied correctly and remain accurate.

VIII. HUMAN FACTORS STUDY

A human factors study in accordance with "Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering to Medical Devices," dated Feb. 3, 2016 to further validate the Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe's use.

IX. BIOCOMPATIBILITY

Biocompatibility testing for all the materials of the syringe has been performed and found acceptable per ISO10993-1: 2009/(R) 2013. The testing includes the acceptable tests for Cytotoxicity, Irritation, Sensitization, Systemic Toxicity and Hemacompatibility as per the individual associated parts of the ISO10993 series.

X. CONCLUSIONS

The information provided supports the substantial equivalence of Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe to the predicates.