November 7, 2018

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

Re: K180683
Trade/Device Name: Certa Dose Pediatric Midazolam 5mg/mL IM Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QDM
Dated: October 4, 2018
Received: October 5, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S

for 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)*
K180683

Device Name
Certa Dose™ Pediatric 5 mg/mL IM Syringe

Indications for Use *(Describe)*
The Certa Dose™ Pediatric Midazolam 5 mg/mL intramuscular (IM) Syringe is intended for the delivery of midazolam 5 mg/mL for use in pediatric (non-neonatal) patients up to 30kg in weight.

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
K180683

I. SPONSOR AND CORRESPONDENT

Sponsor:
Certa Dose, Inc.
7351 E Lowry Blvd. #400
Denver, CO 80230

Submission Correspondent:
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Suite 700
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Date: November 7, 2018

II. DEVICE

Name of Device: Certa Dose™ Pediatric Midazolam 5 mg/mL IM Syringe
Classification Regulation: Piston Syringe, 21 CFR 880.5860
Regulatory Class: II
Product Code: QDM, Midazolam Syringe

III. PREDICATE DEVICES

Predicate: Monoject 1mL Tuberculin Syringe, K851090
Reference Device: Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe, K160589

IV. DEVICE DESCRIPTION

The Certa Dose™ Pediatric Midazolam 5 mg/mL IM Syringe is comprised of (A) a 510(k)-cleared Monoject 1mL Tuberculin Syringe with a regular tip, non-luer lock (K850190), 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, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0 mL, (4) color bars, and (5) the name of the drug for which the syringe is indicated, midazolam 5 mg/mL.

V. INDICATIONS FOR USE

The Certa Dose™ Pediatric Midazolam 5 mg/mL Intramuscular (IM) Syringe is intended for the delivery of Midazolam 5 mg/mL for use in pediatric (non-neonatal) patients up to 30kg in weight.

VI. SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICES

The Certa Dose™ Pediatric Midazolam 5 mg/mL Intramuscular (IM) Syringe ("CD Midazolam Syringe") is substantially equivalent to the Predicate, as it has

(1) the same intended use, and

(2) the same technological characteristics as the Predicate, or where it has different technological characteristics, they do not adversely affect the device safety or effectiveness relative to the Predicate, and do not raise different questions of safety or effectiveness.

1. The CD Midazolam Syringe Has the Same Intended Use as the Predicate and Other Piston Syringes

The intended use of the device is identical to the Predicate: the delivery of fluid. The indication differs from that of the Predicate 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 (e.g., the Reference Device). Further, the decision-making factors that FDA provides in its guidance for evaluating whether a specific indication falls within a general intended use[1] support the conclusion that the intended use of the CD Midazolam Syringe is the same as those of the Predicate.

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

The CD Midazolam Syringe is identical to the Predicate and Reference Device, except for a few differences, which are summarized below.

ATTRIBUTE	CD MIDAZOLAM SYRINGE	PREDICATE
a. Drug and Device Compatibility	Midazolam 5 mg/mL	General Compatibility
b. Color Zones and Other Drug-Specific Barrel Markings	Midazolam-specific color zones that aid as a confirmatory check on volume to be administered. In addition, markings indicate that the product is for intramuscular administration of 5 mg/mL midazolam only.	No color zones or drug-specific recommendations are included on the markings.
c. Text Barrel Marking Specifications	Applied using plastic overlay	Applied directly to barrel

Each of these differences is discussed in detail below.

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

a. Drug and Device Compatibility

The design of the CD Midazolam Syringe is appropriate for delivering midazolam. The syringe components that come into contact with the drug are standard nonreactive materials used in syringe construction – clarified radiation grade polypropylene (barrel material), styrene butadiene rubber, SBR (plunger tip material), and silicone (lubricant). The materials are non-reactive, and in contact with midazolam for a short time. Validation testing was also performed and confirmed compatibility of the syringe and midazolam 5g/mL.

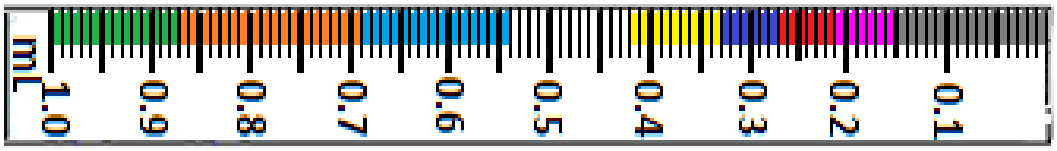
b. Color Zones and Other Drug-Specific Barrel Markings

i. Color Zones

The color zones (bars of color) on the syringe provide an aid in confirming the drawn volume of fluid. 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. The color zones used on the syringe – which are included in the proposed instructions for use and reproduced below – align with standard FDA-approved dosing recommendations.

Standard Pediatric Color Coding System for Weight			Syringe zolam
Color	**Weight Range**	**Volume Range (mL)**	**Amount of Midazolam (mg)**
Grey	3-5 kg	0.00 - 0.15	0 - 0.75
Pink	6-7 kg	0.16 - 0.21	0.76 - 1.05
Red	8-9 kg	0.22 - 0.27	1.06 - 1.35
Purple	10-11 kg	0.28 - 0.33	1.36 - 1.65
Yellow	12-14 kg	0.34 - 0.42	1.66 - 2.10
White	15-18 kg	0.43 - 0.54	2.11 - 2.70
Blue	19-23 kg	0.55 - 0.69	2.71 - 3.45
Orange	24-29 kg	0.70 - 0.87	3.46 - 4.35
Green	30-36 kg	0.88 - 1.08	4.36 - 5.40

Illustration 1: Certa Dose™ Color Zones
Midazolam 5mg/mL concentration (0.15 mg/kg dose) IM



Given that (1) the color zones on the syringe are simply additional visual aids to the graduation markings using a universal color system that is widely adopted and familiar to medical professionals within the pediatric community, (2) healthcare providers routinely use markings on syringes to evaluate the volume of fluid that will be delivered, and (3) the color zones align with FDA-approved dosing recommendations these technological differences do not raise new questions with regard to safety or effectiveness.

ii. Drug Name and Administration

The barrel-markings include the name and concentration for which the drug is indicated, as well as the FDA administration recommendations (intramuscular administration). The fundamental question raised for all barrel markings, including these, is whether they can be understood. For example, a question with regard to the Predicate's markings would be whether the users understood the marked volumes were in milliliters based on inclusion of the "mL" on the barrel.

Given that (1) the markings align with accurate representations (e.g., that the device is indicated for use with midazolam 5 mg/mL only), (2) healthcare providers routinely use markings on syringes to understand their use (e.g., the volumetric measures), and (3) the recommendation for intramuscular administration align with FDA-approved dosing recommendations, these technological differences do not raise new questions of safety or effectiveness.

c. Application of Barrel Markings

The application of barrel markings either through use of direct application of ink to the barrel (as used with the Predicate) or the use of a plastic overlay (as employed with the CD Midazolam Syringe) raise the same questions with respect to safety and effectiveness, namely (1) are the markings accurate and visible, and (2) do they remain accurate and visible over the shelf life of the product after processing? Consequently, no new questions are raised by this technology change. The application of barrel markings in this manner has been validated with shelf-life and volumetric accuracy testing, and did not adversely affect safety or effectiveness.

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™ Midazolam Syringe is substantially equivalent to the Predicate.

VII. **PERFORMANCE TESTING**

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

- Human factors testing to ensure device usability
- 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.
- Break loose and glide force testing was conducted to assure adequacy for the intended use.

VIII. Human factors testing

The assessment of substantial equivalence is supported by the previously submitted human factors study in the reference device, K160589 for the CD Epinephrine Syringe, which included comparative assessments with a standard (non-color coded) 1 mL syringe (also, the current standard of care for administering midazolam). Based on our threshold analysis, below, we believe that the available information provided by this study can be used to support the device design, labels, and labeling for the CD Midazolam Syringe. This determination is based on the facts that (1) all critical tasks regarding the CD Epinephrine Syringe apply to the CD Midazolam Syringe, and (2) the products are highly similar or identical nature with respect to design features; intended users, uses and use environments; labels and labeling; and packaging.

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.

The polymer materials used for the syringe components (barrel and plunger) are identical to the Monoject 1 mL Tuberculin Syringe (previously marketed device) in formulation, processing, and sterilization, and no other chemicals have been added to these components (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

X. STERILIZATION AND SHELF LIFE

1. Sterilization

The device is sterilized by gamma irradiation. The validation method for the sterilization cycle is set forth in BS EN ISO 11137-2:2015, and the dosage of gamma irradiation used for sterilization is determined in accordance with Method 1 of FDA-recognized consensus standard ISO 11137-2:2015.

2. Shelf Life

The currently established shelf life of the product is one-year, based upon (i) the established shelf-life of syringes manufactured and marketed under the Predicate, K850190 (which exceeds a year), plus (ii) one-year real-time stability testing data that was done to assess the integrity of the plastic overlays that contain barrel markings (including color zones). The latter data were obtained using real-time testing with the 510(k)-cleared Certa Dose™ PD Epinephrine 1 mg/mL IM/SC Syringe (K160589) which uses the same plastic overlay materials, processing and colors as the Certa Dose Midazolam Syringe.

XI. CONCLUSIONS

Based on the above, the *Certa Dose™ Pediatric Midazolam 5 mg/mL IM Syringe* is substantially equivalent to the Predicate. The intended use of the *Certa Dose™ Pediatric Midazolam 5 mg/mL IM Syringe* is the same as that of the predicates and the technological changes in the product does not raise any new questions with respect to safety or effectiveness, and the product is substantially equivalent to the Predicate.