November 6, 2023

Revital Healthcare (EPZ) Limited
℅ Atonu Dutta
CEO
Alceon Medtech Consulting
1008, 10th Floor, "OCEAN", Sarabhai Compound Near Centre Square mall, Dr. V.S. Marg Vadodara, Gujarat 390007
India

Re: K231519
Trade/Device Name: Revital Cady
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
Dated: October 4, 2023
Received: October 10, 2023

Dear Atonu Dutta:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231519

Device Name
REVITAL CADY

Indications for Use *(Describe)*
Auto-Disable Syringe is used to administer intramuscular / intravenous medicines or fixed dose immunization.

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.

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K231519 510(K) Summary

1. Submission Sponsor

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3. Date of preparing the summary

11/4/2023

4. Device Details

Table 1: Device details

Device name (Generic):	Hypodermic Auto Disable Syringe with Needle
Device name (Trade Name):	Revital Cady
Classification Regulation:	21 CFR 880.5860, 21 CFR880.5570
Device Class:	Class II
Product Code:	FMF, FMI
Panel:	General hospital

5. Predicate Device

Table 2: Predicate Device

Subject Device Manufacturer	Subject Device	Primary Predicate Device 510K	Secondary Predicate Device510K
Revital Healthcare (EPZ) Limited	Auto Disable Syringe with Needle for Fixed Dose Immunization	K210464	K211214 (For Needle)

6. Device Description

The Revital Cady is an Auto Disable Fixed Dose Immunization Syringe. It is a three-piece Syringe having male 6% luer slip connection. The Syringe is supplied sterile with non-integrated Needle having female 6% luer slip connection. The device is sterilized by ETO gas. It is a disposable, single use and non-pyrogenic device. The Syringe is available in volume of 0.5ml and packed with a needle of 23G size. It is individually packed in blister pouch.

The Syringe has an early activation auto disable feature. When the plunger is pulled back, it is connected to a stainless-steel clip inside the barrel and the auto-disable feature is activated at the start of dose administration. After completion of administration, the plunger is detached from the gasket by pulling back.

The Syringe consist of four components i.e.

1. Barrel
2. Plunger
3. Gasket
4. S.S Clip

The barrel is made of Polypropylene (PP) with graduated scale printed on its outer wall. The barrel has a nozzle with 6% male luer slip connector that facilitates the connection with the female luer slip connection of the needle. The graduated scale on barrel is indicated in millimetres.

The plunger is a solid rod made of Polypropylene. It is used to draw fluid in and out of the barrel by pulling and pushing. The plunger has small rectangular holes on which a clip is fitted. The clip is made up of stainless steel and it is use to activate the auto disable feature. The gasket is made up of PTFE and fitted on top of the plunger.

The Syringe is supplied with a Hypodermic Needle. The Needle is made of three components i.e.

1. Needle tube
2. Needle hub
3. Needle cap

The Needle is made up of stainless steel and bonded to the Needle hub by epoxy and UV glue. The hub and cap of the Needle is made of Polypropylene. The cap is used to protect the needle tip from damage as well as injury.

Raw Materials:

Table 3: Raw Materials

Components	Material	Grade	CAS No.	Type of Body Contact
Syringe				
Barrel	Polypropylene	RG568MO	9003-07-0	Indirect contact with blood path
Plunger	Polypropylene	RG568MO	9002-88-4	Indirect contact with blood path
Gasket	Thermoplastic elastomer	3250-01	66070-58-4	Indirect contact with blood path
Clip	Stainless Steel	SS304	-	No Contact
Needle				
Needle tube	Stainless steel	SS304	Not applicable	Direct contact with blood path
Needle cap	Polypropylene	RG568MO	-	No contact
Needle hub	Polypropylene	RG568MO	-	No contact

- **Indication for use:**

Auto – Disable Syringe is used to administer intramuscular / intravenous medicines or for fixed dose immunization.

7. Comparison to a predicate device

1. Comparison of Auto Disable Syringe to Predicate device

Description	Subject Device (K231519)	Primary Predicate Device (K210464)	Comparison
Product	Auto Disable Syringe with Needle	Auto Disable Syringe	Same
Product code	FMF	FMF	Same
Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Same
Class	II	II	Same
Indication for Use	Auto – Disable Syringe is used to administer intramuscular / intravenous medicines or for fixed dose immunization.	The AUTO DISABLE SYRINGE is intended for use in the suction and injection of vaccine for medical purposes. Additionally, after injection to the body, the plunger can be automatically locked by the triggered mechanism to prevent the re-use of this syringe.	Same
Technological Characteristics			
Configuration	Barrel Plunger Gasket Clip	Barrel Plunger Gasket Clip	Same
Materials	Barrel - Polypropylene Plunger - Polypropylene Gasket- Thermoplastic Elastomer Clip- Stainless Steel	Barrel - Polypropylene Plunger - Polypropylene Gasket- Polyisoprene Rubber Clip- Stainless Steel	**Different 1**
Reuse Prevention (Safety) Feature	Auto – Disable, prevents syringe re-use	Auto – Disable, prevents syringe re-use	Same
Auto disable feature activation	Automatically Activate	Automatically Activate	
Type of Needle	Non-integrated	Integrated	**Different 2**

Description	Subject Device (K231519)	Primary Predicate Device (K210464)	Comparison
Dose Setting / Volumes	Fixed dose: 0.5 ml	0.05ml, 0.10ml, 0.20ml, 0.25ml, 0.30ml, 0.40ml, 0.50ml, 1.0ml	Same (Predicate device have some additional volume sizes syringes)
Barrel transparency	Transparent & Clear	Transparent & Clear	Same
Lubricant	Silicon Oil	Silicon Oil	Same
Biocompatibility	1. Cytotoxicity 2. Sensitization 3. Irritation or Intracutaneous reactivity 4. Acute systemic toxicity 5. Material mediated pyrogenicity 6. Hemocompatibility	1. Cytotoxicity 2. Sensitization 3. Irritation or Intracutaneous reactivity 4. Acute systemic toxicity 5. Material mediated pyrogenicity 6. Hemocompatibility	Same
Syringe Performance	Complied with ISO 7886-3, ISO 7886-1, ISO 9626, ISO 80369-7, ISO 7864	Complied with ISO 7886-3, ISO 7886-1, ISO 9626, ISO 7864	Same
Sterilization Method	EO Sterilized	EO Sterilized	Same
Single Use	Yes	Yes	Same
Shelf Life	5 years	5 years	Same
Labeling	Complies with 21 CFR Part 801	Complies with 21 CFR Part 801	Same

2. Comparison of Needle to Predicate Device

Description	Subject Device (K231519)	Secondary Predicate Device (211214)	Comparison
Class	Class II	Class II	Same
Indication for Use	Auto – Disable Syringe is used to administer intramuscular / intravenous	The sterile hypodermic needles for single use are intended to used with a luer lock or luer slip syringe and	**Different 3**

Description	Subject Device (K231519)	Secondary Predicate Device (211214)	Comparison
	medicines or for fixed dose immunization.	injection devices for general purpose fluid injection/aspiration	
Regulatory number	21 CFR Part 880.5570	21 CFR Part 880.5570	Same
Product code	FMI	FMI	Same
Configuration	Needle Hub Needle Cap (Protective cover) Needle	Needle Hub Protective cover Needle	Same
Materials			
Needle Hub	Polypropylene	Polypropylene	**Different 4**
Needle	Stainless steel	Stainless steel	
Needle Cover	Polypropylene	Polypropylene	
Technical specification			
Needle gauge	23 G	30G, 27G, 26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G	Same- (Predicate device have some additional gauge sizes)
Nozzle type	Luer-Slip	Luer-lock/ Luer-Slip	Same- (Predicate device has additional nozzle type)
Needle hub color	Deep Blue (Color coded as per ISO 6009)	Color coded as per ISO 6009	Same
Hub/needle bond strength	Complies as per ISO 7864:2016	Complies as per ISO 7864:2016	Same
Needle performance	ISO 9626, ISO 80369-7, ISO 7864	ISO 9626, ISO 80369-7, ISO 7864	Same

Substantial Equivalence Discussion:

Different 1:

Thermoplastic Elastomer has a property of elasticity, low Young's modulus and high yield strain. They are permeable and at ambient temperature relatively soft and deformable. Their primary uses are for seals, adhesives, and molded flexible parts[1]. However, the device is tested in accordance with ISO 7886-3:2020, ISO 7886-1:2017, ISO 80369-7:2016, ISO

7864:2016, ISO 9626:2016 standards and results were found satisfactory. The device has also cleared all biocompatibility testing. Considering these factors, the difference of material does not create any safety issue and would perform as intended. Hence, the difference can be considered acceptable.

Different 2:

The Hypodermic Auto Disable Syringe comes with integrated and non-integrated type of Needle. The performance of both type of Needle should comply to ISO 7886-3:2020 clause 12. The auto disable syringe manufactured by Revital Healthcare (EPZ) limited comes with non- integrated Needle. The non-integrated needle is tested according to ISO 7886-3:2020 clause 12, and results were found satisfactory. The device has also cleared other performance test required as per ISO 7886-3:2020, ISO 7886-1:2017, ISO 80369-7:2016, ISO 7864:2016, ISO 9626:2016 standards and results were found satisfactory. Considering these factors, the difference of type of Needle does not create any safety issue and would perform as intended. Hence, the difference can be considered acceptable.

Different 3:

The predicate device has an integrated needle, and the subject device has a non-integrated needle. To prove substantial equivalence of the subject device's non-integrated needle, the secondary predicate is selected. However, the subject device needle intends to be used with the subject device syringe only; therefore, the indications for use are considered the same for both the syringe and the needle. Additionally, the non-integrated needle was tested as per ISO 7886-3:2020, ISO 7864:2016, ISO 9626:2016, ISO 80369-7:2021 standard requirements, and the results met the acceptance criteria. Considering these factors, the difference of type of Needle does not create any safety issue and would perform as intended. Hence, the difference can be considered acceptable.

Different 4:

The material grade for the predicate device is unknown; therefore, it is considered different in comparison to Table 2. However, the subject device materials were tested for biocompatibility, and the results were acceptable. Considering these factors, the material difference creates no safety issue and the device would perform as intended. Hence, the difference can be considered acceptable.

8. Summary of non-clinical performance data

Non-clinical tests were conducted to verify that the proposed device met all design specifications, and is Substantially Equivalent (SE) to the predicate device and reference device.

STANDARDS	TEST PARAMETERS

ISO 7886-1:2017	ISO 7886-1 Second edition 2017-05 - Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7886-3:2020	ISO 7886-3 Second edition 2020-05 - Sterile hypodermic syringes for single use - Part 3: Auto-disabled syringes for fixed-dose immunization
ISO 9626:2016	ISO 9626 Second edition 2016-08-01 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
ISO 80369-7:2021	ISO 80369-7 Second edition 2021-05 - Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 7864:2016	ISO 7864 Fourth edition 2016-08-01 - Sterile hypodermic needles for single use - Requirements and test methods
USP <71>	Sterility tests
USP <85>	Bacterial endotoxin test
USP <788>	Particulate contamination test
Biocompatibility Test:	
• Cytotoxicity, ISO 10993-5:2009 • Acute Systematic Toxicity, ISO 10993-11:2017 • Skin Sensitization, ISO 10993-10:2021 • Intracutaneous Reactivity, ISO 10993-23:2021 • Hemolysis (Direct & Indirect), ISO 10993-4:2017 & ASTM F756-17 • Material Mediated Pyrogenicity	
Packaging & Transits Study:	
ISO 11607-1:2019 2nd edition - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems ISO 11607-2:2019 2nd edition -Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems	
Sterilization Test:	
ISO 11135:2014/AMD 1:2018 2nd edition - Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices.	
EO Residual Test:	
ISO 10993-7:2008/Amd 1:2019 2nd edition- Biological evaluation of medical devices - Part 7:	

Ethylene oxide sterilization residuals, and it meets the requirements of the standard.
Bacterial Endotoxin Test:
The Bacterial endotoxin testing of subject devices was performed by the “Gel-Clot Method” and meets the requirement of USP <85>.

9. Summary of clinical performance data

No clinical study is included in this submission.

10. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.