February 5, 2024

Clear Choice Therapeutics
% Cynthia Pritchard
CEO
BioTechnology Transfer, LLC
1016 Tobiano Lane
Raleigh, North Carolina 27614

Re: K232379
Trade/Device Name: PREVENT™ Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 3, 2024
Received: January 5, 2024

Dear Cynthia Pritchard:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known):* K232379

Device Name
PREVENT™ Kit

Indications for Use *(Describe)*

The PREVENT™ Kit is intended to be used as an alternative to foam and other negative pressure wound therapy dressings when used in conjunction with the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps (K082311) for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT1 or CCT Mini Negative Pressure Wound Drainage Pumps, the PREVENT™ Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudate, infectious material and tissue debris.

The PREVENT™ Kit is appropriate for use on the following wounds:

- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-Operative and Dehisced Surgical Wounds
- Skin Flaps and Grafts

The system is for prescription use only.

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 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Sponsor/Applicant Name and Address

Company Name: Clear Choice Therapeutics, Inc.

Address: 310 S. West Street, Suite 200, Raleigh, NC 27603

Telephone: (919) 743-2500 (office) or 919-345-1836 (mobile)

Contact Person: Bret A. Batchelder

Title: CEO

Date Summary Prepared: 2 February 2024

Device Name and Classification

Trade Name:	PREVENT™ Kit
21 CFR Section:	21 CFR 878.4780
Regulation Name:	powered suction pump
Product Code:	OMP
Classification:	Class II
Panel:	General and Plastic Surgery

Predicate Device

THEIA NPWT Wound Foam Dressing Kit, K211277

Device Description

The PREVENT™ Kit is used with the CCT1 and CCT Mini NPWT Drainage Pumps for negative pressure wound therapy (NPWT). NPWT uses a closed drainage system to apply controlled suction (vacuum) to a wound bed. The wound is first dressed with a single layer Prevent™ barrier (dressing) to allow pressure to be distributed evenly to the wound bed. The wound is then sealed with an adhesive film drape. A dome drainage tube is connected to the dressing through an opening of the film drape. The drainage tube is connected to a canister on the side of the vacuum pump. The vacuum may be applied continuously or intermittently, depending on the type of wound being managed and the clinical objectives.

Indications for Use

The PREVENT™ Kit is intended to be used as an alternative to foam and other negative pressure wound therapy dressings when used in conjunction with the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps (K082311) for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT1 or CCT Mini Negative Pressure Wound Drainage Pumps, the PREVENT™ Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudate, infectious material and tissue debris.

The PREVENT™ Kit is appropriate for use on the following wounds:

- Pressure Ulcers
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- Post-Operative and Dehisced Surgical Wounds
- Skin Flaps and Grafts

The system is for prescription use only.

Kit Contents

1. (2) 10x12 in. transparent adhesive film drapes
2. (1) Dome Assembly consisting of ported dome with skirt and connection tube including clamp and Luer lock connection
3. (1) Prevent™ barrier, 20 cm X 25 cm
4. Instructions for Use (IFU)

The CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps are not provided with the PREVENT™ Kit. Please refer to the CCT1 and CCT Mini Negative Pressure Wound Drainage Pump User Manual and follow the recommendations for use.

Device Comparison Table

Parameter	Subject Device	Primary Predicate Device
	PREVENT™ Kit	Theia Foam Kit
Company Name	Clear Choice Therapeutics (CCT)	Clear Choice Therapeutics (CCT)
510(k) #	232379	K211277
Classification name	Negative Pressure Wound Therapy Powered Suction Pump	Negative Pressure Wound Therapy Powered Suction Pump
Classification panel	General and Plastic Surgery Devices (DHT4B)	General and Plastic Surgery Devices (DHT4B)
Class	II	II
21 CFR number	878.4780	878.4780
Category	Powered suction pump and wound dressing kit	Powered suction pump and wound dressing kit
Product Code	OMP	OMP
Device Description	The PREVENT™ Kits are composed of sterile, single-use, disposable components that are designed to be used with a pump to deliver NPWT to a wound surface as part of a negative pressure wound therapy (NPWT) system. The dressing kit includes 1) a thermoplastic elastomer (TPE) dressing (Prevent™ barrier) used to contact the wound bed and allow the application of NPWT to the wound and to provide flow pathways for the removal of exudate, 2) occlusive drape(s) to create a seal around the wound, and 3) a dome assembly with drainage tubing that is connected to the suction tubing of the disposable canister of the negative pressure pump to create a closed system. The negative pressure pump creates a vacuum that provides the suction needed to remove wound exudate from the wound surface to the collection canister. The wound contact layer is provided in a single size and thickness, so the kits are provided in a single size.	The Theia Foam Kits are composed of sterile, single use, disposable components for use with negative pressure pumps as part of a negative pressure wound therapy (NPWT) system. The dressing kit includes 1) a foam dressing used to contact the wound bed and allow the application of NPWT to the wound and to provide flow pathways for the removal of exudate, 2) occlusive drape(s) to create a seal around the wound, and 3) a dome assembly with drainage tubing that is connected to the suction tubing of the disposable canister of the negative pressure pump to create a closed system. The negative pressure pump creates a vacuum that provides the suction needed to remove wound exudate from the wound surface to the collection canister. The kits are provided in small, medium, and large sizes (based on foam dressing length x width) with an additional option of foam thickness for wound packing and coverage.

Parameter	Subject Device	Primary Predicate Device
Kit Components	• Prevent™ barrier, 20 cm x 25 cm • Dome assembly consisting of ported dome with skirt and connection tube including clamp and Luer lock connection • [2] Drapes	• Foam Dressing (three sizes: large 25 x 16cm, medium 20 x 13cm, and small is 10 x 8cm. each available in 3 cm and 1.5 cm thickness) • Dome assembly consisting of ported dome with skirt and connection tube including clamp and Luer lock connection • [1 or 2] Drapes
Wound contact layer	The Prevent™ barrier is a flexible transparent component of thermoplastic elastomer (Medalist MD-10135 Natural). This component is intended for use as the primary contact layer, applied in direct contact with the wound surface.	The Theia foam is a black, reticulated flexible polyether-based polyurethane hydrophobic foam material with 60 pores per square inch. This component is intended for use as the primary contact layer, applied in direct contact with the wound surface.
Skin Contact Layer (Drape)	2.5mil 3M 9836 Clear polyolefin carrier 1.0 mil 3M 9836 Polyurethane Film 3M 9836 Acrylate adhesive designed for medical / surgical use	2.5mil 3M 9836 Clear polyolefin carrier 1.0 mil 3M 9836 Polyurethane Film 3M 9836 Acrylate adhesive designed for medical/surgical use
Intended Use / Indications for Use	The PREVENT™ Kit is intended to be used as an alternative to foam and other negative pressure wound therapy dressings when used in conjunction with the CCT1 and CCT Mini Negative Pressure Wound Drainage Pumps (K082311) for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT1 or CCT Mini Negative Pressure Wound Drainage Pumps, the PREVENT™ Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudate, infectious material and tissue debris. The PREVENT™ Kit is appropriate for use on the following wounds: • Pressure Ulcers • Diabetic/Neuropathic Ulcers • Venous Insufficiency Ulcers • Traumatic Wounds • Post-Operative and Dehisced Surgical Wounds • Skin Flaps and Grafts The system is for prescription use only.	The Theia NPWT Foam Wound Dressing Kit is intended to be used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pump for the application of negative pressure wound therapy to the wound. The Theia NPWT Foam Wound Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris. The Theia NPWT Foam Wound Dressing Kit is appropriate for use on the following wounds: • Pressure Ulcers • Diabetic/Neuropathic Ulcers • Venous Insufficiency Ulcers • Traumatic Wounds • Post-Operative and Dehisced Surgical Wounds • Skin Flap and Grafts The system is appropriate for use in acute, extended and homecare settings.

Parameter	Subject Device	Primary Predicate Device
Principles of Operation	The wound bed is dressed, fitted with mode of communication between the wound bed and suction apparatus, and sealed (according to labeling instructions). The suction apparatus is engaged to create a vacuum (negative pressure) within the wound bed drives the wound exudate to be pumped from the wound bed into a collection canister. The device is designed to provide a pre-set level of negative pressure to the wound bed.	The wound bed is dressed, fitted with mode of communication between the wound bed and suction apparatus, and sealed (according to labeling instructions). The suction apparatus is engaged to create a vacuum (negative pressure) within the wound bed drives the wound exudate to be pumped from the wound bed into a collection canister. The device is designed to provide a pre-set level of negative pressure to the wound bed.
Maximum Duration of a single dressing	3 days	3 days
Dressing changes	• Follow hospital protocol, policy, and procedure for using NPWT dressings and pumps. • With a heavily colonized or infected wound, consider changing the dressing every 12 to 24 hours. Regular monitoring of the wound must be maintained to check for signs of infection	• Follow hospital protocol, policy, and procedure for using NPWT dressings and pumps. • With a heavily colonized or infected wound, consider changing the dressing every 12 to 24 hours. Regular monitoring of the wound must be maintained to check for signs of infection.
User Population	Healthcare professionals	Healthcare professionals
Patient Population	Adults	Adults
Use Environment	Healthcare facilities and home care settings	Healthcare facilities and home care settings
Canister Volume	900 ml	900 ml
Pump	Pump; Exsudex™ Negative Pressure Wound Drainage Pump models XS and XL, privately labeled as CCT Mini and CCT1 Negative Pressure Wound Drainage Pumps, respectively	Pump; Exsudex™ Negative Pressure Wound Drainage Pump models XS and XL, privately labeled as CCT Mini and CCT1 Negative Pressure Wound Drainage Pumps, respectively
Pump Type	Custom designed pump controlled by a microprocessor	Custom designed pump controlled by a microprocessor
Pump power source	AC or battery	AC or battery
Pressure intensity (NPWT operating ranges)	Pump spec indicates range is -10 to -200 mmHg; nominal pressure at the wound surface is 120 mmHg	Pump spec indicates range is -10 to -200 mmHg; nominal pressure at the wound surface is 120 mmHg
Sterility	Kit components are supplied sterile; SAL 10^{-6}	Kit components are supplied sterile; SAL 10^{-6}

Parameter	Subject Device	Primary Predicate Device
Sterilization method	Ethylene oxide; validated to ISO / AAMI 11135-1 Medical Devices - Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and AAMI / ANSI / ISO 10993-7 Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	Gamma irradiation

Comparison Summary

The kits are composed of sterile, single-use components to be used for NPWT, and each component of both kits has the same function. The main difference between the two devices is that the wound contact layers are of different formats, sizes and materials.

Each side of the Prevent™ barrier (wound contact layer) has a unique geometry to allow for efficient flow of fluids and negative pressure.). The transparent Prevent™ barrier, drape and dome assembly allow visibility of the wound bed, and the TPE dressing is hydrophobic.

The PREVENT™ Kit is sterilized with EO, whereas the Theia Foam Kit is gamma irradiated, but both have been validated to meet the SAL requirements.

Performance Summary

Bench Testing

Performance testing included 7-day Glass Top Simulated Use, Tensile Testing [Dome assembly to Tubing Connection], Tensile Strength of the Prevent™ barrier, Seal Strength and Bubble Emission tests of the primary sterile barrier, and System Alarm Functionality. All tests of the device met the pre-determined acceptance criteria.

Shelf-Life

The data from all three sets of accelerated aging tests confirm that the PREVENT™ Kit device meets the requirements as tested and reported within the document series. Real-time, long-term shelf life testing on the PREVENT™ Kit was completed for one year and confirmed the acceptable results of one year accelerated aging. Real-time testing will continue to a minimum of two years to confirm acceptable results to support the targeted two-year shelf-life.

Safety Summary

Biocompatibility Testing

GLP (21 CFR Part 58) biocompatibility testing of the PREVENT™ Kit included cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute / subchronic systemic toxicity, and implantation, per ISO 10993-1:2018. EO residuals (ISO 10993-7:2008) and bacterial endotoxin tests (Limulus Amoebocyte Lysate (LAL) Test) are done on each lot of sterilized devices. All tests of the device met the pre-determined acceptance criteria.

GLP Animal Testing

A new GLP (21 CFR Part 58) study was completed to compare the wound healing and tissue response of the CCT PREVENT™ Kit to a marketed control article and to show that the CCT PREVENT™ Kit is as safe and effective as a marketed control article over the course of 35 +/- 1 days in swine. The following endpoints were considered: animal health, wound healing, and local histological effects.

All endpoints were evaluated per protocol for this study and met the pre-determined acceptance criteria. Based on evaluation of overall animal health, wound healing performance and local tissue response to the study articles, there were no concerns identified regarding the safety and effectiveness of CCT PREVENT™ Kit.

Usability Testing

A Human Factors / Usability Validation study was done per ISO / IEC 62366-1:2015. Results indicate that the CCT PREVENT™ Kit is appropriate for use by the intended users in the intended use environments. Fifteen enrolled participants performed a simulated use scenario of applying the Prevent™ barrier, draping the wound, connecting the dome assembly and tubing to the drape, initiating NPWT, pausing NPWT, and removing and disposing of the wound materials. None of the participants were trained, and had to perform the tasks relying only on the user interfaces of the system and the IFU.

The study population collectively performed 272 individual subtasks that were evaluated for performance. Of those individual subtasks, 249 were classified as being performed successfully, without UEs, difficulties, or close calls. Only 10 use errors were observed and none of these would cause harm of a serious nature.

Conclusion

The differences between the subject and predicate devices do not raise any new issues of safety or effectiveness. The subject device performed as well as the control device in the 35-day GLP study. Therefore, we conclude that the PREVENT™ Kit is substantially equivalent to the predicate devices.