December 16, 2021

Clear Choice Therapeutics, Inc.
% Kathy Herzog
Regulatory Consultant
DuVal & Associates
1820 Medical Arts Building, 820 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K211277
Trade/Device Name: Theia NPWT Foam Wound Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 17, 2021
Received: September 20, 2021

Dear Kathy Herzog:

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/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 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 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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K211277

Device Name
Theia NPWT Foam Wound Dressing Kit

Indications for Use *(Describe)*
The Theia NPWT Foam Wound Dressing Kit is intended to be used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps, 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

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Clear Choice Therapeutics, Inc.
530 W. Cloverhurst Ave.
Athens, GA 30606-4216

Phone: 217.377.4834

Contact Person: John Prince
Date Prepared: November 18, 2021

II. DEVICE

Trade/Proprietary Names:	Theia NPWT Foam Wound Dressing Kit, Models UN1083S, UN20133M, and UN25163L, FWTS21, FWTM36, and FWTL44
Common Name:	Foam Dressing Kit
Regulation Number:	21 CFR 878.4780
Regulation Name:	Powered Suction Pump
Device Class:	II
Product Code:	OMP
Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Theia NPWT Foam Wound Dressing Kit, K161570.

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Theia NPWT Foam Wound Dressing Kits are sterile, single use, disposable dressings for use with the CCT Mini or CCT1 Negative Pressure Wound Drainage pumps for the application of negative pressure wound therapy (NPWT) to the wound. The kits include a foam dressing made of black reticular polyether based polyurethane hydrophobic foam material, occlusive drape(s), and a dome assembly consisting of a single lumen dome, dome skirt, and drainage tubing with clamp and female luer lock connector. The foam

dressing covers the wound and the transparent occlusive drape covers the foam dressing and creates a seal around the wound. The drainage tubing connects to the exudate canister of the negative pressure pump. The powered negative pressure pump delivers negative pressure to the dressing to suction wound exudate into the exudate canister of the pump. The dressing kits are available in three sizes (small, medium, large) based on foam dressing size (length x width) and in two foam dressing thicknesses (1.5 and 3.0 cm), for a total of six dressing kits.

The Theia NPWT Foam Wound Dressing Kits are for institutional use only with the CCT Mini and CCT1 pumps cleared through K082311.

V. INDICATIONS FOR USE

The Theia NPWT Foam Dressing Kit is intended to be used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps, the Theia NPWT Foam 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 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject (1.5cm thick foam dressing) and predicate (3.0cm thick foam dressing) Theia NPWT Foam Wound Dressing Kits have the same Intended Use for the application of NPWT to the wound when used in conjunction with a negative pressure pump. The 1.5cm and 3.0cm thick foam dressing kits are identical except for the foam thickness, kit model numbers, and indicated negative pressure pumps as shown in Table 1.

Table 1: Subject vs. Predicate Theia NPWT Foam Wound Dressing Kit Comparison

Feature	Theia NPWT Dressing Kit (Subject Device)	Theia NPWT Dressing Kit (Predicate Device)
K Number	K211277	K161570
Classification	21 CFR 878.4780	21 CFR 878.4780
Product Code	OMP	OMP
Class	II	II
Intended Use	The Theia NPWT Dressing Kit is intended to be used in conjunction with a negative pressure pump for the application of negative pressure wound therapy to the wound.	The Theia NPWT Dressing Kit is intended to be used in conjunction with a negative pressure pump for the application of negative pressure wound therapy to the wound.
Indications For Use	The Theia NPWT Foam Wound Dressing Kit is intended to be used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps for the application of negative pressure wound therapy to the wound. When used in conjunction with the CCT Mini or CCT1 Negative Pressure Wound Drainage Pumps, 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 Theia NPWT Foam Wound Dressing Kit is intended to be used in conjunction with the SIMEX Negative Pressure Wound Therapy Pumps (K113291) for the application of negative pressure wound therapy to the wound. When used in conjunction with the SIMEX Negative Pressure Wound Therapy Pumps, 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
Type of Use	Prescription Only	Prescription Only
User	Healthcare professional	Healthcare professional
Intended Use Environment	Hospital or long-term care clinic setting	Hospital or long-term care clinic setting

Feature	Theia NPWT Dressing Kit (Subject Device)	Theia NPWT Dressing Kit (Predicate Device)
Single Use or Reusable	Single Use	Single Use
Foam Dressing Dimensions and Model Numbers	Model Number, Size, and dimensions (Length x Width x Thickness, in cm). • Model FWTS21 (Small): 10x8x1.5 • Model FWTM36 (Medium): 20x13x1.5 • Model FWTL44 (Large): 25x16x1.5	Dimensions stated as Length x Width x Thickness in cm. Three sizes (small, medium, and large) in one thickness: • Model UN1083S (Small): 10x8x3 • Model UN20133M (Medium): 20x13x3 • Model UN25163L (Large): 25x16x3
Kit Components	One foam dressing, occlusive drape(s) (1 in the small kit and 2 in the medium and large kits), and one dome assembly (dome, skirt, and drainage tubing with luer lock and clamp)	One foam dressing, occlusive drape(s) (1 in the small kit and 2 in the medium and large kits), and one dome assembly (dome, skirt, and drainage tubing with luer lock and clamp)
Kit Component Function	• **Foam wound dressing** is used to pack the wound. • **Occlusive drape** creates and maintains a seal over the peri-wound area and foam dressing. • **Dome Assembly** provides a pathway for wound exudate to flow from the wound/dressing to the pump exudate canister.	• **Foam wound dressing** is used to pack the wound. • **Occlusive drape** creates and maintains a seal over the peri-wound area and foam dressing. • **Dome Assembly** provides a pathway for wound exudate to flow from the wound/dressing to the pump exudate canister.
Foam Dressing Material	Black Polyether Polyurethane Foam	Polyether Polyurethane Foam
Dome Material	Thermoplastic Elastomer	Thermoplastic Elastomer
Occlusive Drape Material	Semipermeable, polyurethane (polymeric) transparent film	Semipermeable, polyurethane (polymeric) transparent film
Skirt Material	Polyurethane Medical Tape with Adhesive Backing	Polyurethane Medical Tape with Adhesive Backing
Tubing Material	PVC	PVC
Dressing Materials Biocompatible	Yes	Yes
NPWT pump provided with	No	No

Feature	Theia NPWT Dressing Kit (Subject Device)	Theia NPWT Dressing Kit (Predicate Device)
dressing kit		
Dressing Kit Provided Sterile	Yes	Yes
Sterilization Method	Gamma Radiation	Gamma Radiation
Packaging	Tyvek pouch	Tyvek pouch

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Bench Performance Testing

Bench testing has been performed to demonstrate that the 1.5cm or 3.0cm Theia NPWT Foam Wound Dressing Kits used with the CCT Mini or CCT1 pumps are capable of effectively removing wound fluids and that pressure is delivered uniformly across the dressing and in accordance with the pump pressure setting. The subject NPWT systems performed as intended in the simulated wound and pressure maintenance test setups, and all results were acceptable.

Animal Performance Study

No animal performance studies were conducted for the Theia NPWT Foam Wound Dressing Kit.

Clinical Study

No clinical studies were conducted for the Theia NPWT Foam Wound Dressing Kit.

VIII. CONCLUSIONS

The subject and predicate Theia NPWT Foam Wound Dressing Kits have the same Intended Use. The technological characteristics comparison and results of the verification testing provide evidence that the subject Theia NPWT Foam Wound Dressing Kits are substantially equivalent to the predicate Theia NPWT Foam Wound Dressing Kits (K161570), and the performance of these dressing kits when used in conjunction with CCT pumps (K082311) is substantially equivalent to the performance of the predicate dressing kits used in conjunction with SIMEX pumps (K113291).