June 23, 2026

CG Bio Co., Ltd.
Youngwook Moon
1, Sangwon 12-Gil, Seongdong-Gu
Seoul, 04791
Republic Of Korea

Re: K253199
Trade/Device Name: CURASYS 2 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 20, 2026
Received: May 20, 2026

Dear Youngwook Moon:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MUSTAFA A. MAZHER -S

For Yu-Chieh Chiu PhD,
Assistant Director
DHT4B: Division of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253199

Device Name
CURASYS 2 Negative Pressure Wound Therapy System

Indications for Use *(Describe)*

The CURASYS 2 Negative Pressure Wound Therapy (NPWT) System is an integrated wound management system for use in acute and extended care settings.

When used on open wounds, it is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

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.

K253199

1. Submitter Information

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Date Prepared: May 20, 2026

2. Device Information

Trade/Device Name: CURASYS 2 Negative Pressure Wound Therapy System
Common Name: Powered suction pump for negative pressure wound therapy
Regulation Name: Powered suction pump
Regulation Number: 21 CFR 878.4780
Product Code: OMP
Device Class: Class II

3. Predicate Device Information

ACTIV.A.C.™ NPWT System, K201571
KCI / 3M

4. Device Description

The CURASYS 2 Negative Pressure Wound Therapy (NPWT) System is a portable, software-controlled negative pressure suction device intended to deliver controlled negative pressure to a wound site through an NPWT dressing kit.

The system consists of the CURASYS 2 pump unit, disposable suction canister, connecting tubing, power cord, hanger, and user instructions. The CURASYS 2 pump unit provides negative pressure, monitors pressure status, and provides user alarms for conditions such as full canister, air leak, low battery, and tube blockage.

For performance testing, the CURASYS 2 system was evaluated with the CUDP0510 dressing configuration from the KulaVAC Foam Dressing Kit family, which was cleared under 510(k) K122490.

The CURASYS 2 pump unit may be operated using AC power or its rechargeable lithium-ion battery. AC power is the primary power configuration during normal use, while the internal battery supports temporary operation during patient movement, relocation, or temporary interruption of external power. The battery is not intended to be the sole normal-use power source for continuous therapy.

The device provides continuous and cyclic negative pressure therapy modes. In continuous mode, the device delivers and maintains the selected negative pressure continuously. In cyclic mode, the device alternates between a high-pressure setting and a low-pressure setting according to the programmed cycle.

5. Indications for Use

The CURASYS 2 Negative Pressure Wound Therapy (NPWT) System is an integrated wound management system for use in acute and extended care settings.

When used on open wounds, it is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

6. Technological Characteristics

The CURASYS 2 NPWT System has the same general technological characteristics as the predicate device. The device uses an electrically powered suction pump to generate controlled negative pressure and deliver that negative pressure to the wound site through tubing and an NPWT dressing kit. Wound exudate is transported through the tubing and collected in a disposable suction canister.

The CURASYS 2 system includes pressure control, continuous and cyclic therapy modes, rechargeable battery support, visual and audible alarm functions, and a user interface for therapy setting and monitoring. The alarm functions include full canister, air leak, low battery, and tube blockage conditions.

A comparison of the technological characteristics of the subject device and predicate device is provided below.

Feature	**Subject Device — CURASYS 2 NPWT System**	**Primary Predicate — ACTIV.A.C.™ NPWT System, K201571**	
Regulation / Class / Product Code	21 CFR 878.4780 / Class II / OMP	21 CFR 878.4780 / Class II / OMP	
General device type	Powered NPWT pump system	Powered NPWT pump system	
Use environment	Acute, extended, and home care settings	Acute, extended, and home care settings	
Therapy modes	Continuous and cyclic therapy modes	Continuous and intermittent therapy modes	
Negative pressure range	-10 to -200 mmHg	-25 to -200 mmHg	
Pressure adjustment	5 mmHg increments	Predicate-specific settings	
Canister	Disposable suction canister, 350	Disposable canister, 300	

	mL	mL	
Exudate management	Exudate collected in disposable canister; backflow prevention function	Exudate collected in disposable canister	
Alarm functions	Canister full, air leak, tube blockage, low battery	Comparable alarm categories, including blockage, canister, low battery, and leak-related alarms	
Power source	AC power with rechargeable lithium-ion battery support	AC power / battery-powered portable operation	
Battery use	Rechargeable internal battery supports temporary operation during patient movement or temporary loss of AC power	Battery-supported portable operation	
Electrical safety / protection	IEC 60601-1 tested; Type BF applied part; IP32	IEC 60601-1 tested	
Software-controlled operation	Yes	Yes	
Portability	Portable reusable pump unit with hanger accessory	Portable reusable pump unit	
Dressing compatibility	Compatible NPWT dressing kit; performance testing conducted using the CUDP0510 dressing configuration from the KulaVAC Foam Dressing Kit family, K122490	Compatible NPWT dressing kit	

7. Summary of Nonclinical Testing

Nonclinical testing was performed to support substantial equivalence of the CURASYS 2 NPWT System. The nonclinical testing included electrical safety, electromagnetic compatibility, software verification and validation, usability engineering, bench performance testing, performance qualification testing, full-duration simulated-use testing.

Bench Performance Testing

Bench performance testing was performed to support the safety and performance of the CURASYS 2 system. The testing included the following:

- Negative pressure accuracy;
- Suction flow rate;
- Operating noise;
- Electrical safety testing in accordance with applicable IEC 60601-1 requirements;
- Electromagnetic compatibility testing in accordance with applicable IEC 60601-1-2 requirements, including emissions and immunity;
- Software verification and validation for the software-controlled pump unit;
- Performance qualification testing of final finished devices from three lots; and
- Full-duration simulated-use testing under cyclic negative pressure operation for a continuous 5-day simulated-use period.

8. Summary of Clinical Testing

Clinical testing was not performed. Clinical data were not required to demonstrate substantial equivalence.

9. Conclusion

The CURASYS 2 Negative Pressure Wound Therapy System has the same intended use and similar technological characteristics as the predicate device. The differences between CURASYS 2 and the predicate device do not raise different questions of safety or effectiveness.

Based on the nonclinical performance testing, electrical safety testing, electromagnetic compatibility testing, software verification and validation, usability engineering evaluation, full-duration simulated-use testing, and shelf-life rationale, the CURASYS 2 Negative Pressure Wound Therapy System is as safe and effective as, and performs as well as, the predicate device.