March 18, 2025

Global Healthcare SG Sdn. Bhd
Keng Liang Cheng
Managing Director
Lot 43824, Jln Tech Valley 2/1, Bandar Sri Sendayan
Seremban
Negeri Sembilan, 71950
Malaysia

Re: K240933
Trade/Device Name: CarbonCool System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NZE
Dated: February 21, 2024
Received: November 20, 2024

Dear Keng Liang Cheng:

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.

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural, and Vascular Devices
OHT2: Office of Cardiovascular 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.

Submission Number *(if known)*

K240933

Device Name

CarbonCool® System

Indications for Use *(Describe)*

Temperature reduction for adult patients where clinically indicated, e.g., in hyperthermic patients.

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 of Safety and Effectiveness for CarbonCool® is provided in accordance with 21 CFR 807.92.

Date:	19 Mar 2024
Submitter (Owner):	Ms. Geetha Ganesh Medra+ Pte. Ltd., 6 Kitchener Link, 05 - 11, Singapore - 207227 Phone: +65 9135 7048 E-mail Id: geetha@medraplus.com
510(k) Contact Person:	Mr. Siow Ming Qian Global Healthcare SG Sdn. Bhd Lot 43824, Jln Tech Valley 2/1, Bandar Sri Sendayan, 71950 Seremban, Negeri Sembilan, Malaysia Phone: +65 9725 9715 E-mail Id: jacksiow@globalhealthcare.sg
Device Trade Name:	CarbonCool® System
Regulation Number:	21 CFR 870.5900
Regulation Name:	Thermal regulating system
Classification Panel:	Cardiovascular
Device Class:	Class II
Product Code:	NZE
Predicate Device:	EMCoolspad (**K100071**) **Regulation number:** 21 CFR 870.5900 **Regulation Name:** Thermal regulating system **Device class:** II **Product code:** NZE **Review panel**: Cardiovascular

1. **Indications for Use:**

   Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients.

2. **Description of the Device:**

   Global Healthcare SG has developed the CarbonCool® products as a portable, non-invasive body cooling solution designed to enhance temperature reduction for adult patients. The CarbonCool® also enables more widespread applications by reducing treatment cost and increasing treatment flexibility and accessibility.

The model numbers included in the submission are indicated below:

MODEL NAME	MODEL NO
MPad™	MP-FPS729-001
MPad™ Large	MPL-FPS123-001
CarbonCool® XTend™	XT-FPS001-001
CarbonCool® XTend™ Large	XTL-FPS001-001
Detachable TPU (non-sterile)	DT-FPS1-002
CarbonCool® OmniPad™	OP-FPS3-002
CarbonCool® Full Body Suit™	FB-FPS20-002
CarbonCool® Abdomen Pad Holder	AB-FPS6-002
CarbonCool® Chest Pad Holder	CH-FPS8-002
CarbonCool® Thigh Pad Holder	TH-FPS3-002
CarbonCool® Comfort Suit™	CS-FPS14-002
CarbonCool® Vest	CV-FPS6-003
CarbonCool® Vest Set	CVS-FPS6-003
CarbonCool® Comfort Suit V™	CSV-FPS14-003
CarbonCool® Military Vest	CMV-FPS14-003
CarbonCool® Wrap I™	CCWI-FPS20-003

3. Physics and Mechanism Summary:

3.1 Cooling Duration and Skin Temperature:

CarbonCool employs a Pad Holder design to optimize heat exchange efficiency and maintain consistent skin contact.

3.2 Heat Exchange Mechanism:

The Pad Holder minimizes ambient temperature interference, allowing for effective transfer of heat from the skin to the cooling pad.

3.3 Enhanced Efficiency:

By reducing air gaps and ensuring a snug fit against the patient's skin, CarbonCool maximizes the effectiveness of heat exchange.

3.4 Device Performance:

CarbonCool offering enhanced comfort and efficacy for medical cooling applications and confirms that this device is as safe and effective as the predicate device.

In summary, CarbonCool's innovative Pad Holder design and efficient heat transfer mechanism ensures optimal cooling performance and temperature regulation.

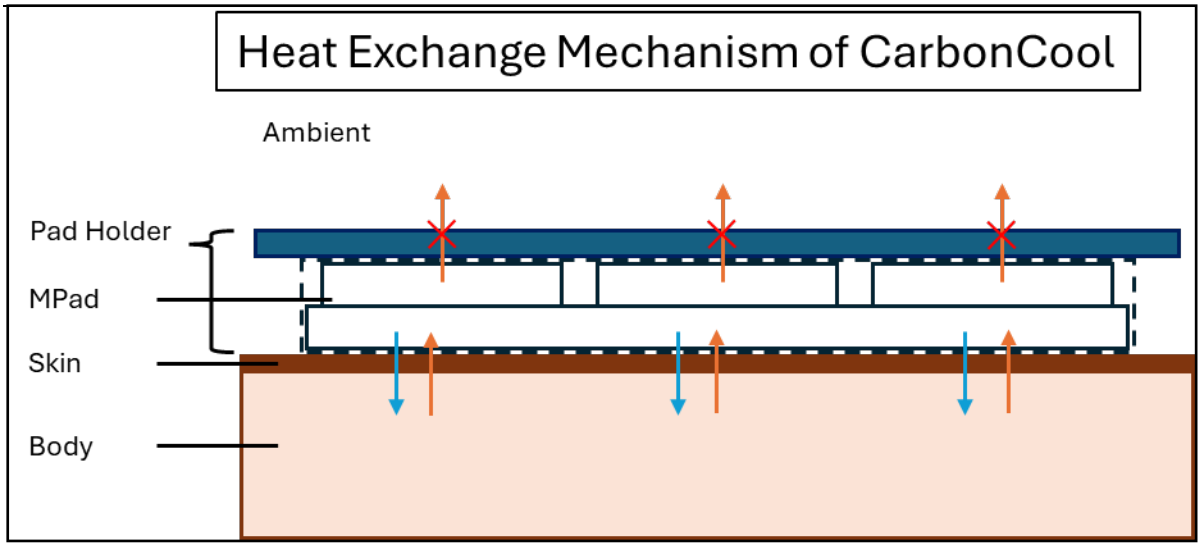

Figure 1: Heat Exchange Mechanism of CarbonCool

4. Comparison to Predicate Devices:

One predicate device is selected in this submission for the substantial equivalence discussion of CarbonCool® Systems. Please refer to Table 1 for detailed substantial equivalence discussion.

Predicate device: **EMCoolspad – Predicate device**

Table 1: Predicate Device Comparison

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
Product Name	CarbonCool® Systems	EMCoolspad – Predicate	NA
Manufacturer	Global Healthcare SG Sdn. Bhd.	Emergency Medical Cooling Systems AG	NA
Regulation Number	21 CFR 870.5900	21 CFR 870.5900	Identical
Product Code	NZE	NZE	Identical
Product Class	2	2	Identical
Indications for Use	Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patients	Temperature reduction for adult patients where clinically indicated, e.g. in hyperthermic patient	Identical
Description	The CarbonCool® System is a single use passive body cooling solution designed for medical and comfort cooling purposes. The CarbonCool® System utilizes the MPad™ which consist of multiple cooling-cells made of thermoplastic polyurethane, filled with high thermal conductivity material.	The EMCOOLSpad is a single use surface (skin) cooling device, which is adherent to the patient's skin and so highly adjustable during the cooling procedure. An EMCOOLSpad consists of multiple cooling-cells made of thermoplastic polyurethane, filled with high thermal conductivity material, stored frozen at 0 to -10°C.	Is almost identical, as MPad™ and EMCOOLspad used the same technology, the only difference is the method of apply on patient's skin. CarbonCool® System's MPad™ recommended to store at -15 to -18°C and and EMCOOLS store at 0 to -10°C.

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
User and patient interface	The patient's core temperature is regulated within in a certain temperature range by manually removing (= warming) or applying (=cooling) the Pad Holder that contain MPad™	The patient's core temperature is regulated within in a certain temperature range by manually removing (= warming) or applying (=cooling) the EMCOOLSpads.	Almost identical as both is apply on patient skin. The only differences is EMCOOLSpads apply directly on the skin with an adhesive layer and CarbonCool® Systems is the MPad™ slot into the Pad Holder and apply on the skin.
Device interface	A commercially available third-party temperature probe connected to a commercially available third-party monitor senses the patient's core temperature.	A commercially available third-party temperature probe connected to a commercially available third-party monitor senses the patient's core temperature.	Identical.
Implantable device	Non-implantable device	Non-implantable device	Identical.
Intended patient Population	adult patients	adult patients	Identical. Both systems are designed for medical applications and are used to provide temperature reduction in patients for specific medical conditions.
Intended use	Used by trained user. It is non-professional use only device.	Used by trained user. It is non-professional use only device.	Identical.

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
Anatomical sites	Patient skin surface	Patient skin surface	Identical.
Use environment	Hospital/ clinic/ Home use	Hospital/ clinic/ Home use	Identical. Both is designed for pre-hospital use and requires no power supply during cooling, making it more portable and suitable for immediate application in emergencies.
Device components	Pad holder, Detachable TPU, MPad	Detachable TPU, Flex Pad	Identical. CarbonCool® System offers better cooling duration with CarbonCool® Pad Holder as insulation and depending on the application and use of CarbonCool® XTend™ for extending cooling duration. EMCOOLS Flex.Pad is direct applied on skin, and one side of the pad is contact with the ambient temperature.
Feature	Non-sterile. Prescription use device. The product is free of latex, PVC, and phthalates.	Non-sterile. Prescription use device. The product is free of latex, PVC, and phthalates.	Identical.

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
Single use/Re use	Single use	Single use	Identical.
Disposable/Non-Disposable	Non-Disposable	Non-Disposable	Identical.
Sterilization	Non-sterile	Non-sterile	Identical.
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Identical.
Materials	MPad is made of HypoCarbon®, Pad holder is made ofT PU, Velcro is made of PVC.	Flex pad is made of HypoCarbon®, Pad holder is made of TPU, Velcro is made of PVC.	Identical. Both systems utilize advanced cooling mediums to achieve effective temperature reduction in patients. CarbonCool® System uses a proprietary carbon-based cooling medium (HypoCarbon®), while EMCOOLS Flex.Pad contains HypoCarbon® as well.
Biocompatibility	• ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing; 2003	• ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing; 2003 • ISO 10993-5: 1999-11; Biological evaluation of medical devices -	

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
	• ISO 10993-5: 1999-11; Biological evaluation of medical devices - Part 5: Tests for cytotoxicity; in vitro methods. • EN ISO 10993-5: 2007, Biological evaluation of medical devices - PartS5: Tests for in vitro cytotoxicity • ISO 10993-10; Biological evaluation of medical devices - Part 10 Test for irritation and delayed hypersensitivity (components).	Part 5: Tests for cytotoxicity; in vitro methods. • EN ISO 10993-5: 2007, Biological evaluation of medical devices - PartS5: Tests for in vitro cytotoxicity • ISO 10993-10; Biological evaluation of medical devices - Part 10 Test for irritation and delayed hypersensitivity (components). • ISO 10993 -12: 2008 -02, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.	
Technological characteristics			
Thermal regulating system	Yes	Yes	Identical.

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
Non-invasive system	Yes	Yes	Identical. Both CarbonCool® System and EMCOOLS Flex.Pad are non-invasive cooling solutions, allowing temperature reduction without the need for invasive procedures.
Patient surface cooling	Yes	Yes	Identical.
Permanent contact to the patient's skin during cooling	Yes	Yes	Identical.
Permanent contact to the patient's skin during cooling	Yes	Yes	Identical.
Removal of thermal energy from the patient	Yes	Yes	Identical.
Removal of thermal energy from the patient	Yes	Yes	Identical.

Comparable Properties	Subject Device	EMCoolspad (K100071) – Predicate Device	Comparison Results
temperature monitoring with a temperature probe (own brand or 3rd party)	Yes	Yes	Identical.
Rewarming function	Yes	Yes	Identical.
Compatible freezer details	Yes	Yes	Both systems require pre-cooling in a freezer before use.
Imaging Compatibility	Yes	Yes	Identical. Both systems are compatible with medical imaging techniques like X-ray, CT, and MRI, enabling medical professionals to perform scans without removing the cooling pads.
Shelf life	36 months	36 months	Identical

Based on the results of risk assessments, biocompatibility evaluation, and compliance with recognized standards demonstrate that the CabonCool® system is as safe and effective as the predicate and therefore is substantially equivalent to the predicate.

5. Summary of Non-Clinical Testing:

- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing; 2003
- ISO 10993-5: 1999-11; Biological evaluation of medical devices - Part 5: Tests for cytotoxicity; in vitro methods.
- EN ISO 10993-5: 2007, Biological evaluation of medical devices - PartS5: Tests for in vitro cytotoxicity
- ISO 10993-10; Biological evaluation of medical devices - Part 10 Test for irritation and delayed hypersensitivity (components).

The tests were conducted by NAMSA, 6750 Wales Road, Northwood, OH 43619. The CarbonCool® System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1: Passed
- Primary packaging testing as per ASTM F1980-21, ASTM F1886/F1886M-16, ASTM F3039-15, ASTM F2096-11, and ASTM F88/F88M-21: Passed
- Useable life of the device of three (3) years

6. Performance Testing – Bench:

The CarbonCool® System utilizes the innovative MPad™ technology encased in a thermal enclosure, providing safe and efficient cooling for various applications. The MPad™, made from flexible yet durable TPU, houses a proprietary carbon-based cooling medium, ensuring rapid heat exchange with the skin. This unique design enables passive cooling after pre-cooling in a freezer, resulting in a portable and cost-effective cooling solution.

In-house testing confirms the high performance of the MPad™, surpassing traditional cooling methods like ice and water. The MPad™ withstands pressure and maintains durability over extended periods, ensuring reliability in critical situations.

7. Conclusion:

Based on the results of risk assessments, biocompatibility evaluation, and compliance with recognized standards demonstrate that the CabonCool® system is as safe and effective as the predicate and therefore is substantially equivalent to the predicate.