November 25, 2025

Stemtech Medical Devices Private Limited
% Giselle Zhang
Lead QA&RA Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K252289
Trade/Device Name: Eva Scalp Cooling System
Regulation Number: 21 CFR 878.4360
Regulation Name: Scalp Cooling System To Reduce The Likelihood Of Chemotherapy-Induced Alopecia
Regulatory Class: Class II
Product Code: PMC
Dated: July 23, 2025
Received: July 23, 2025

Dear Giselle Zhang:

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,

Jessica Carr -S

Jessica Carr, PhD
Assistant Director
DHT4A: Division of General 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)*
K252289

Device Name
Eva Scalp Cooling System

Indications for Use *(Describe)*
The Eva Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

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

Eva Scalp Cooling System

1. Submission Sponsor

Stemtech Medical Devices Private Limited

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Title: Lead QA&RA Consultant

3. Date Prepared

04/15/2025

4. Device Identification

Trade/Proprietary Name:	Eva Scalp Cooling System
Common/Usual Name:	Scalp Cooling System
Regulation Number(s):	878.4360
Product Code(s):	PMC, Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.
Class:	II
Classification Panel:	General & Plastic Surgery

5. Legally Marketed Predicate Device(s)

Device name: DigniCap Delta Scalp Cooling System
510(k) number: K191166
Manufacturer: Dignitana, Inc.

The DigniCap Delta Scalp Cooling System ("DigniCap Delta") is a device that is intended to function as a cooling system to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. The proposed therapy of the new device is comparable to the therapy of the predicate device, DigniCap Scalp Cooling System (K170871).

DigniCap Delta cools fluid to a prescribed set temperature and circulates that cooled fluid through a cooling wrap and then back to the device. This mode of operation is equivalent to other scalp cooling devices. User operation of the DigniCap Delta system is carried out on the illuminated graphics display with the integrated touch control, located on the front of the unit. The navigation and selection buttons on the display are used to interface with the device.

6. Device Description

The Eva Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. The Eva Scalp Cooling System is a cooling unit with a built-in control system. It can be operated using a touch-screen display. The device maintains a cooling temperature between -3°C and 1°C, and the treatment time can be adjusted by the doctor for before, during, and after chemotherapy. The treatment time also can be adjusted by doctor for different cancer types and drug types. The system features a computerized control unit that keeps the scalp temperature steady during treatment.

7. Indication for Use Statement

The Eva Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

8. Substantial Equivalence Discussion

The following table compares the Eva Scalp Cooling System to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Comparison of Characteristics

Attribute	**Subject: Eva Scalp Cooling System**	**Predicate: DigniCap Delta Scalp Cooling System**	**Comparison**
510(k) Number	/	K191166	
Product Code	PMC	PMC	Same
Regulation Number	§878.4360	§878.4360	Same
Regulation Name	Scalp Cooling System	Scalp Cooling System	Same

Attribute	Subject: Eva Scalp Cooling System	Predicate: DigniCap Delta Scalp Cooling System	Comparison
Indications for Use	The Eva Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.	The DigniCap Delta Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.	Same
Designed for Use	Hospitals and healthcare facilities	Hospitals and healthcare facilities	Same
Environment of Use	Ambient temperature 10 - 30°C, relative humidity 30 - 75%	Temperature: 10°C – 25°C Relative Humidity: 30% to 60%, non-condensing	Different
Mechanism of Action	The Eva Scalp Cooling System transports temperature-controlled cooled fluid from the device to a cooling cap to cool the patient's scalp, thereby reducing chemotherapy-induced alopecia.	The DigniCap Delta Scalp Cooling System transports temperature-controlled cooled fluid from the device to a cooling cap to cool the patient's scalp, thereby reducing chemotherapy-induced alopecia.	Same
Technology Overview	The unit is composed of the main unit that contains the refrigeration components, touch screen controller, and coolant tank. There are detachable coolant lines with covers, detachable cooling cap with covers, and proprietary coolant.	The DigniCap Delta Scalp Cooling System consists of a solid-state thermoelectric cooling unit with integral control system operated via a touchscreen monitor, capable of precisely controlling the temperature of one cooling cap.	Different
Patient Population	Chemotherapy Patients with Solid Tumors.	Chemotherapy Patients with Solid Tumors.	Same
Set Cooling Time	Yes	Yes	Same
Pre/Post Cooling Time	Yes	Yes	Same
Material of Cooling Cap	Neoprene (Outer Cover)	Neoprene (Outer Cover)	Same
	Thermoplastic polyurethane (TPU)	Polyacrylic, nylon	Different
Size of Cooling Cap	Adjustable	Adjustable	Same
Inner Cooling Cap	With adjustable tabs Single Patient Use	With adjustable tabs Single Patient Use	Same
Outer Cooling Cap	Single Patient Use	Single Patient Use	Same
Number of Cooling Caps/Lines	2	1	Different

Attribute	Subject: Eva Scalp Cooling System	Predicate: DigniCap Delta Scalp Cooling System	Comparison
Quick Disconnect	Yes	Yes	Same
Coolant Temperature Range	-3 to 1°C	-7 to 1.5°C	Different
Sensors	The temperature of the fluid is regulated by temperature sensors located in the coolant reservoir.	The temperature of the fluid is regulated by temperature sensors located in the fluid lines.	Different
Refrigerant Type	Proprietary mixture (Propylene glycol +water)	Isopropyl alcohol/water mixture	Different
Coolant Refilling	Yes	Yes	Same
Sterile	No	No	Same
Single-Use	No	No	Same
Main Unit Dimensions	1140(L)x460(H)x480(W)mm	952.5(L)x 508 (D) x 381 (W) mm	Different
Weight	80 kg (Eva Cooling Unit)	65kg	Different
AC Powered	230 V, 50/60 Hz	100-240 V, 50/60 Hz	Different
Touch Screen Interface	Yes	Yes	Same
Software Controlled	Yes	Yes	Same
Use Life	12 sessions	NA	Different
Battery Operated	NA	Yes	Different
Complies with ISO 10993-1	Pass	Pass	Same
Electrical Safety Testing	Pass	Pass	Same
Electromagnetic Compatibility Testing	Pass	Pass	Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Eva Scalp Cooling Cap and to show substantial equivalence to the predicate device, Stemtech completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Eva Scalp Cooling passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Irritation testing per ISO 10993-23 – Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 and IEC 60601-4-2 – Passed

- Software verification and validation per IEC 62304/FDA Guidance – results /conclusion
- Shelf-Life Testing – Supports shelf life of 1 years
- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained
- Thermal Performance
- Stable Fluid Temperature Verification
- Flow Rate Verification
- Fluid Containment and Leakage Test
- System Integration Test
- Cleaning Validation Test

10. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

11. Statement of Substantial Equivalence

The Eva Scalp Cooling Cap has the same intended use as the predicate device and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Based on the results of the risk assessment and all applicable testing, the Eva Scalp Cooling Cap is determined to perform as intended during normal anticipated usage and is at least as safe, as effective, and performs as well as or better than the legally marketed predicate device and therefore can be determined to be substantially equivalent to the predicate device.