December 18, 2024

Caerus Corporation
% Jean-Marie Toher
Regulatory Consultant
MEDIcept Inc
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K241395
Trade/Device Name: Active System; Avenue8
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: ILX, IRT, IMD
Dated: December 2, 2024
Received: December 2, 2024

Dear Jean-Marie Toher:

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,

Vivek J. Pinto -S

Vivek Pinto, PhD, MBA
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K241395

Device Name
Active System; Avenue8

Indications for Use *(Describe)*
The Active System and Avenue8 are indicated for adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.

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

I. SUBMITTER

510(k) Holder: Caerus Corporation
8611 W 35W Service Dr NE Ste 180
Blaine, MN 55449

Contact Person: Jean-Marie Toher
Regulatory Consultant
MEDIcept, Inc.
jtoher@medicept.com

Date Prepared: December 18, 2024

II. DEVICES

Trade Name: Active System
Classification Name: Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat
Regulatory Class: Class II
Product Codes: ILX - Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat
IMD - Hot Or Cold Disposable Pack

Trade Name: Avenue8
Classification Name: Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat
Regulatory Class: Class II
Product Codes: ILX - Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat
IRT – Powered Heating Pad

III. PREDICATE DEVICES

Primary Predicate: K121702 – OrthoCor Active Device
Secondary Predicate (Active System): K092044 – OrthoCor Knee Active System
Secondary Predicate (Avenue8): K202337 – HiDow Pulsed electromagnetic field wrap

IV. DEVICE DESCRIPTION

The Caerus Active System is a portable, compact, lightweight, non-invasive system designed to deliver transcutaneous pulsed electromagnetic field (non-thermal shortwave diathermy) and thermal exchange

therapy. The Active System includes general use wraps and therapy is delivered with single-use OrthoPods, sold separately.

The Caerus Avenue8 device is a portable, compact, lightweight, non-invasive system designed to deliver transcutaneous pulsed electromagnetic field (non-thermal shortwave diathermy) therapy and electronic heat.

V. INDICATIONS FOR USE

The Active System and Avenue8 are indicated for adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.

VI. INTENDED USE

The Active System is intended to be worn for one two-hour treatment of 2 30-minute non-thermal shortwave diathermy treatments per day by adult users. For prescription use (Rx) only.

The Avenue8 is intended to be worn for two 30-minute treatments per day by adult users. For prescription use (Rx) only.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate devices and the subject devices is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences (Table 1 and Table 2). The technological characteristic differences do not raise different questions of safety and effectiveness than the predicate device.

Table 1. Substantial Equivalence Subject Device Active System (K241395) Compared to the Predicate Devices OrthoCor Active Device (K121702) and OrthoCor Knee Active System (K092044)

Characteristic	OrthoCor Active System (K241395)	OrthoCor General Use Device (Primary Predicate) K121702	OrthoCor Active Knee System (Secondary Predicate) K092044	Equivalence Comparison
Regulatory Class	Class II	Class II	Class II	Same
Regulatory Number	21 CFR 890.5290(b) 21 CFR 890.5710	21 CFR 890.5290(b)	21 CFR 890.5290(b) 21 CFR 890.5710	Same

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Characteristic	OrthoCor Active System (K241395)	OrthoCor General Use Device (Primary Predicate) K121702	OrthoCor Active Knee System (Secondary Predicate) K092044	Equivalence Comparison
Regulation Name	Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat	Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat	Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat	Same
Product Code	ILX, IMD	ILX	ILX, IMD	Similar
Indication for use	Adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue. Temporary relief of minor aches and pains associated with overexertion, strains, sprains, and arthritis.	Performance testing justified substantial equivalence
Anatomical site	General Use	General Use	Knee	Similar
Frequency – short wave	27.12 MHz	27.12 MHz	27.12 MHz	Same
Output Impedance	50 Ohm	50 Ohm	50 Ohm	Same
Burst Frequency	2 Hz	2 Hz	2 Hz	Same
Therapy Control Burst Width	2 ms	2 ms/PPR | 2Hz	2 ms/PPR | 2Hz	Same
Exposure	1 hour	30 minutes	30 minutes	Performance testing justified substantial equivalence
Energy Deposited Via	Induction Coil	Induction Coil	Induction Coil	Same
Peak Generator Power	1.35 W	.5 W	.5 W	Performance testing justified substantial equivalence
Heating Method	Chemical	NA	Chemical	Same

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Table 2. Substantial Equivalence Subject Device Avenue8 (K241395) Compared to the Predicate Devices OrthoCor Active Device (K121702) and HiDow Pulsed electromagnetic field wrap (K202337)

Characteristic	Avenue8 (K241395)	OrthoCor General Use Device (Primary Predicate) K121702	HiDow Pulsed Electromagnetic Field Wrap (Secondary Predicate) K202337	Equivalence Comparison
Regulatory Class	Class II	Class II	Class II	Same
Regulatory Number	21 CFR 890.5290(b) 21 CFR 890.5740	21 CFR 890.5290(b)	21 CFR 890.5290 21 CFR 890.5740	Similar
Regulation Name	Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat	Shortwave Diathermy, For Use Other Than Applying Therapeutic Deep Heat	Shortwave Diathermy	Similar
Product Code	ILX, IRT	ILX	ILX, IRT	Similar
Indication for use	Adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue. It is also indicated for the temporary relief of minor aches and pains associated with overexertion, strains, sprains, and arthritis.	Performance testing justified substantial equivalence
Anatomical site	General Use	General Use	General Use	Same
Frequency – short wave	27.12 MHz	27.12 MHz	27.12 MHz	Same
Output Impedance	50 Ohm	50 Ohm	Not Publicly Available	Same
Burst Frequency	2 Hz	2 Hz	Not Publicly Available	Same
Therapy Control Burst Width	2 ms	2 ms/PPR | 2Hz	Not Publicly Available	Same
Exposure	1 hour	30 minutes	Not Publicly Available	Performance testing justified substantial equivalence

Characteristic	Avenue8 (K241395)	OrthoCor General Use Device (Primary Predicate) K121702	HiDow Pulsed Electromagnetic Field Wrap (Secondary Predicate) K202337	Equivalence Comparison
Energy Deposited Via	Induction Coil	Induction Coil	Not Publicly Available	Same
Peak Generator Power	1.35 W	.5 W	Not Publicly Available	Performance testing justified substantial equivalence
Heating Method	Electrical	NA	Electrical	Same

VIII. PERFORMANCE DATA

Non-clinical performance testing was conducted to verify the subject device performance. The following performance data was provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC):
The systems comply with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing:
The software is classified as a Basic Level of Documentation. Testing and documentation for a Basic Level of Documentation are provided in the submission in compliance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (June 2023)

Non-Clinical Testing Summary:

The following testing was conducted to satisfy the under the Special Controls under regulation 890.5290(b):

- Peak output power;
- Pulse width;
- Pulse frequency;
- Duty cycle;
- Characteristics of other types of modulation that may be used;
- Average measured output powered into the RF antenna/applicator;

- Specific absorption rates in saline gel test load or other appropriate model;
- Characterization of the electrical and magnetic fields in saline gel test load or other appropriate model for each RF antenna and prescribed RF antenna orientation/position; and
- Characterization of the deposited energy density in saline gel test load or other appropriate model.
- Temperature testing was completed on participants of varying skin types to demonstrate that the devices were capable of maintaining a skin temperature of 40 – 45 degrees Celsius for 20 minutes.

Clinical Study:
In compliance with the special controls for regulation 890.5290(b), a clinical study was performed. 120 patients were enrolled, 48 in the Active System (Shortwave Diathermy + Heating Therapy) group and 43 in the SOC group, both males and females, over 18 years of age, with a history of pain in superficial soft tissue, such as in the ankle, back, knee, wrist, elbow, shoulder, foot, or neck. The incidence of adverse events in this study was notably low, with only 3.3% of participants (4 out of 120) experiencing minor complications. These events were distributed equally across both the Active System + Standard of Care (SOC) and Standard of Care (SOC) groups. The nature of these events were mild, consisting of shoulder pain, sleepiness, discomfort associated with the device wrap, and a tingling or numb sensation in the cervicothoracic region. Critically, there were no reports of serious adverse events or unanticipated adverse device effects. The lack of significant complications and the minimal
occurrence of adverse events reinforces the safety profile of the Active System treatment, affirming its suitability for clinical use in pain management.

This study was conducted in compliance with the Special Controls under regulation 21 CFR 890.5290(b)(2)(iv). The study examined the change from baseline in pain assessment scores at the end of 2 weeks of study treatment using the Mankowski scale. The SOC group experienced a 10% reduction in pain while the Active System + SOC group had 36% reduction in pain.

The findings from this clinical study report establish the Active System as an adjunctive therapy is a significantly more effective intervention for pain management in soft tissue injuries, than Standard of Care (SOC) alone as outlined in the study protocol. Specifically, the study primarily enrolled participants in the foot, knee and shoulder groups. The clinical data was clinically meaningful in the foot, knee and shoulder.

IX. CONCLUSIONS

The substantial equivalence tables and performance testing results demonstrate that the Caerus Corporation Active System and Avenue8 devices are substantially equivalent to the OrthoCor Active Device.

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