September 13, 2024

Ivy Biomedical Systems, Inc.
Felicia Piel
Vice President, QA/RA
11 Business Park Drive
Branford, Connecticut 06405

Re: K240087
Trade/Device Name: RT Carbon ECG Leads
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA, DRX
Dated: August 16, 2024
Received: August 16, 2024

Dear Felicia Piel:

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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.

510(k) Number *(if known)*
K240087

Device Name
RT Carbon ECG Leads

Indications for Use *(Describe)*
The Ivy Biomedical RT Carbon ECG Leads are intended for use in X-ray imaging environments. They connect between ECG electrodes that are placed on the patient by a trained healthcare professional and an ECG trunk cable that connects to the ECG monitoring device. The RT Carbon ECG Leads are reusable and nonsterile. The RT Carbon ECG Leads are intended for adult, pediatric and neonatal patient populations.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1 Applicant

Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, CT 06405
Phone: (203) 481-4183
Fax: (203) 481- 8734

2 Primary Contact

Felicia Piel
Vice President, QA/RA
Direct: (203) 643-9933
felicia.piel@ivybiomedical.com

3 Preparation Date: November 7th, 2023

4 Device Name

Proprietary Name:	RT Carbon ECG Leads
Common/ Usual Name:	RT Carbon ECG Leads

5 Device Classification

Establishment Registration Number:	1221108
Classification Name:	Patient transducer and electrode cable (including connector)
Classification Regulation:	21 CFR 870.2900
Device Classification:	Class II
Product Code:	DSA

6 Device Description

The RT Carbon ECG Leads are intended to connect electrodes placed on the patient to a physiological detection module or monitor (CTM-300, CTM-400, CTM-500, 7000 Series and 3000 Series). The design includes 3 and 4 lead designs with overall lengths of 24", 30" and 36".

7 Intended Use

The Ivy Biomedical RT Carbon ECG Leads are intended for use in X-ray imaging environments. They connect between ECG electrodes that are placed on the patient by a trained healthcare professional and an ECG trunk cable that connects to the ECG monitoring device. The RT Carbon ECG Leads are reusable and nonsterile. The RT

carbon ECG Leads are intended for adult, pediatric and neonatal patient populations.

8 Predicate Device

Predicate	Clearance 510(k)
Vital Connections Stealthshield	[K970755]

9 Technical Characteristics

The RT Carbon ECG Leads have the same technical characteristics as the predicate Vital Connections Stealthshield [K970755]. It is a 3 or 4 lead, non-magnetic, carbon lead set.

The RT Carbon ECG Lead sets primary differences from the predicate are listed below:

- The Stealthshield [K970755] is sold in a 40" variation

10 Comparison of Technological Characteristics with the Predicate Device

ECG monitoring is the technological principle for both the subject and the predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

- Connect to ECG electrodes
- Intended for use in X-ray imaging environments
- Shieleded ECG Plug EC53 compliant connector
- Grabber clip leads
- RF shielded
- 3 or 4 lead wires

11 Performance Data

a. Biocompatibility Testing

The biocompatibility evaluation for the RT Carbon ECG Leads was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing'" May 1, 1995, and Internation Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part I: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. This includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

- Systemic Toxicity
- Pyrogen Testing

The Ivy Biomedical RT Carbon ECG Lead Wires categorization by duration of contact under section 5.3 is Limited Exposure (A). The use of the RT Carbon ECG Leads during prep and scan is limited and less than 24 hours.

b. Performance Testing

The RT Carbon ECG Leads were assessed, thoroughly tested from design requirements through device verification and validation testing as required by 21 CFR 870.2900. The following bench testing was completed at Ivy in accordance to EC53:

- Patient Leadwire to Trunk Cable Interconnection
- Flex life
- Tensile strength
- Connector mating/unmating cycles
- Connector retention force
- Contact resistance
- Leadwire resistance
- Dielectric withstand voltage

12 Animal Study

Animal studies were not performed.

13 Clinical Test Conclusion

Clinical trials were not performed.

14 Non-Clinical Test Conclusion

The performance data support the safety of the device and hardware verification and validation demonstrate that the RT Carbon ECG Leads should perform as intended in the specified use conditions and is substantially equivalent to the predicate.