January 27, 2022

Energetic Designs, Inc.
% John Gillespy
President
FDA 510k Consultants, LLC
1100 Del Lago Circle #104
Palm Beach Gardens, Florida 33410

Re: K211941
Trade/Device Name: 9Line
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: December 22, 2021
Received: December 27, 2021

Dear John Gillespy:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Shih 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211941

Device Name
9Line

Indications for Use *(Describe)*

9Line patient leadwires are intended to be used to connect electrodes placed at appropriate sites on the patient to an ECG or EKG monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional. The device is intended for single-patient use.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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. 510(k) Submitter:

Energetic Designs, Inc.
1100 Del Lago Cir, Palm Beach Gardens, FL
33410 Phone: 386-243-4332
Email: john@fda510kconsultants.com

2. Company Contact: John F. Gillespy, MBA

3. Date of Submission: June 17, 2021

4. 510(k) Preparer:

John F. Gillespy, MBA
FDA 510k Consultants, LLC
Palm Beach Gardens, FL 33410
Phone: 386-243-4332
Email: john@fda510kconsultants.com

5. Device Classification:

Trade name:	9Line
Common name:	ECG Disposable Lead Wires
Device:	Cable, Transducer & Electrode, Patient, (Including Connector)
Class:	II
Regulation #:	870.2900
Product Code:	DSA

6. Predicate:

Applicant:	APK Technology Co.
Device:	ECG Disposable Lead Wires
510(k) Number:	K170536

7. Indications For Use

9Line patient leadwires are intended to be used to connect electrodes placed at appropriate sites on the patient to an ECG or EKG monitoring device for general monitoring and/or diagnostic evaluation by a health care professional. The device is intended for single-patient use.

8. Device Description

9Line is comprised of multiple patient leadwires that connect electrodes affixed to the patient's body either to an external trunk cable or directly into an electrocardiogram (ECG) monitor. Each leadwire connects to a separate patient electrode (see photo of product at right). Leadwires and electrode placement are color-coded in accordance with Association for the Advancement of Medical Instrumentation (AAMI) recommendations.

The device transmits ECG signals from the patient for both diagnostic and monitoring purposes.

9Line is for prescription-use only. The product is sold non-sterile for single-patient use.

9. Device Models

9Line models are shown below:

PART NUMBER	DESCRIPTION (SNAP TERMINATION)
3SS-030	30” 3 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
3SS-050	50” 3 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
5SS-030	30” 5 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
5SS-050	50” 5 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
5VSS-030	30” 5 V Leads Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
5VSS-050	50” 5 V Leads Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-3SS-030	30” 3 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-3SS-050	50” 3 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-6SS-030	30” 6 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-6SS-050	50” 6 Lead Snap Single Patient Use AAMI w/Shielded Systems Bonded Cable

PART NUMBER	DESCRIPTION (PINCH TERMINATION)
3PS-030	30” 3 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
3PS-050	50” 3 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
5PS-030	30” 5 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
5PS-050	50” 5 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
5VPS-030	30” 5 V Leads Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
5VPS-050	50” 5 V Leads Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-3PS-030	30” 3 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-3PS-050	50” 3 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-6PS-030	30” 6 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable
NK-6PS-050	50” 6 Lead Pinch Single Patient Use AAMI w/Shielded Systems Bonded Cable

10.

11. Comparison To Predicate Device

The following table compares **9Line** with the predicate device:

Comparison Table

Characteristics	Device	Predicate	Comparison
Name	**9Line**	ECG Disposable Lead Wires	NA
Applicant	Energetic Designs Inc	APK Technology Co	NA
510k Number	Applied For	K170536	NA
Device Photo			NA
Classification	II	II	Same
Regulation Number	870.2900	870.2900	Same
Product Code	DSA	DSA	Same
Intended Use	Connect patient electrodes with ECG for monitoring or diagnostic evaluation.	Connect patient electrodes with ECG for monitoring or diagnostic evaluation.	Same
Indications For Use	9Line patient leadwires are intended to be used to connect electrodes placed at appropriate sites on the patient to an ECG or EKG monitoring device for general monitoring and/or diagnostic evaluation by a health care professional. The device is intended for single-patient use.	The ECG Disposable Lead Wires are intended to be used with ECG. The lead wire is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.	Same
Target Population	Adults	Adults	Same
Anatomical Site	Upper body	Upper body	Same
Where Used	Health care facility	Health care facility	Same
Reuse	Single patient only	Single patient only	Same
Rx/OTC/Both	Rx	Rx	Same

Physical Characteristics

System Description	ECG lead wires with terminal connectors	ECG lead wires with terminal connectors	Same
Design Concept	Lead wires transmit ECG signals from patient to trunk cable or monitoring device	Lead wires transmit ECG signals from patient to trunk cable or monitoring device	Same
Lengths	30", 50"	50" (per brochure)	Minor difference
Lead Sets	3, 5, 6, 10 (by combining two sets of 5 leads: one limb lead set and one set of vleads)	3, 5, 6, 10 (brochure)	Same
Termination	Snap, Pinch	Snap, Pinch	Same
Multiple Models Based on Features	Yes	Yes	Same
Peelable Ribbon	Yes	Yes	Same
Material Composition	Medical-grade PVC jacket	PVC	Same
Powered	No	No	Same

Components

Shielded Lead Wires	Yes	Yes	Same
Patient Termination Connector	Yes (Snap & Pinch)	Yes (Snap & Pinch)	Same
Trunk/Monitor Connector	Yes	Yes	Same
Trunk Cable	No	No	Same
Accessories	None	None	Same

S&E Testing

Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-5:2009 ISO 10993-10:2010	Same
Electrical Safety	IEC 60601-1:2005 MOD (Part 8.5.2.3)	IEC 60601-1:2005 MOD (Part 8.5.2.3)	Same
Mechanical Safety	ANSI/AAMI EC 53: 2013	ANSI/AAMI EC 53: 2013	Same

The subject device is comparable to the predicate in terms of design, function, materials, and performance. None of the differences raised different issues of safety and effectiveness.

Non-Clinical Testing

9Line passed the following non-clinical tests, all of which were performed to current FDA-recognized standards:

- Biocompatibility, ISO 10993-5:2009 and ISO 10993-10:2010… Device is non-cytotoxic, non-sensitizing, and non-irritating.
- Electrical & Mechanical Safety, IEC 60601-1 (Part 8.5.2.3) and ANSI/AAMI EC 53:2013…

Device meets electrical and mechanical safety standards.

Substantial Equivalence

9Line patient leadwires successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (2014). The steps are summarized below:

- The predicate device is legally marketed and was found substantially equivalent through 510(k) premarket submission.
- The subject and predicate devices have the same intended use (and indications for use).
- Technological differences between the subject and predicate were evaluated; none of the differences raised different issues of safety and effectiveness.
- The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—testing for biocompatibility, electrical safety, and mechanical performance. Evaluation methods were conducted to FDA-recognized standards where applicable.
- Data from these tests demonstrated equivalence and support the indications for use.

In summary, all necessary testing has been performed and the results support the conclusion that **9Line** patient leadwires is substantially equivalent to the legally marketed predicate, based on both (a) comparison of intended use, materials, technology, and design and (b) testing to FDA-recognized standards, and the device thus does not raise any concerns of safety or effectiveness.

Based on the information contained within this submission, the applicant concludes that **9Line** is substantially equivalent to the identified predicate device.