January 17, 2020

Authentic Medical
Ricky Souza
CEO
4470 Yankee Hill Rd., Ste 100
Rocklin, California 95677

Re: K181089
Trade/Device Name: SureLead Disposable Cable System
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: December 10, 2019
Received: December 11, 2019

Dear Ricky Souza:

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
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181089

Device Name
SureLead Disposable Cable System

Indications for Use *(Describe)*
The SureLead Disposable Cable System is intended to be used with ECG monitoring devices. The SureLead Disposable Cable System is used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for generating monitoring and/or diagnostic evaluation by a health care professional.

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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SureLead Disposable Cable System
Traditional 510(k)

SureLead Disposable Cable System
Premarket Notification 510(k) Summary

DATE PREPARED	19 APR 2018
MANUFACTURER	Authentic Medical
CONTACT PERSON	Ricky Souza Position: CEO/President Tel: (916) 952- 6498 Fax: (916) 644-6015 Email: rsouza@authenticmed.com
PANEL CODE	Cardiovascular
CLASSIFICATION	Patient Transducer and Electrode Cable (Including Connector)
CLASS	Class II (Class 2)
COMMON NAME	Cable / Lead-wire
TRADE NAME	SureLead Disposable Cable System
PREDICATE DEVICES	K170536 Cable/Lead-Wire (ECG).
Identification of Proposed Device	Trade Name: Surelead Disposable cable system Common Name: cable/lead-wire

DEVICE DESCRIPTION

The SureLead Disposable Cable System with specific various lengths are the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) and other third-party after-market manufacturers for their respective monitors. These cables consist of connectors on each cable end and a shielded bulk cable. These cables are used to transfer the signals from the electrodes to the patient monitor. The SureLead Disposable Cable System uses the same type of construction and have the same technological characteristics as the predicate device. The SureLead Disposable Cable System is made of medical grade PVC and PP cable jacket with medical grade PVC and PP over molded connectors with integral relief.

INDICATIONS FOR USE

The SureLead Disposable Cable System is intended to be used with ECG monitoring devices. The SureLead Disposable Cable System is used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for generating monitoring and/or diagnostic evaluation by a health care professional.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SureLead Disposable Cable System, is substantially equivalent to the Predicate device (K170536) intended use / indications for use, materials, technological characteristics, and labelling.

PERFORMANCE DATA

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device (K170536). The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.
- AAMI/ANSI EC53: 2013 ECG Trunk Cables and Patient Leadwires
- IEC 60601-1:2005+CORR.1: 2006+CORR. 2:2007+AM1: 2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

SUBSTANTIAL EQUIVALENCE DISCUSSION

The SureLead Disposable Cable System, (Subject Device) is substantially equivalent to K170536 ECG Disposable Cable / lead-wire (Predicate Device).

The Subject device and Predicate Device:

- Have nearly Identical Indications for Use
- Are provided non-sterile with steam sterilization instructions
- Use similar cable lengths and the same materials

Table 1 is provided here to show the comparison.

Table 1: Substantial Equivalence Summary Table

	Proposed Device	Predicate Device K170536	Remarks
Manufacturer	Authentic Medical	APK Technology Co., Ltd	-
510(k) number	K181089	K170536 Cable/Lead-wire	-
Classification Regulation	21 CFR Part 870.2900	21 CFR Part 870.2900	SE
Panel	Cardiovascular	Cardiovascular	SE
Common Name	Cable / Lead-wire	Cable / Lead-wire	SE
Device Classification Name	Patient transducer and electrode cable (including connector)	Patient transducer and electrode cable (including connector)	SE
Product Code	DSA	DSA	SE
Class	Class II (Class 2)	Class II (Class 2)	SE

Indications for Use	The SureLead Disposable Cable System is intended to be used with ECG monitoring devices. The SureLead Cable System is used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for generating, monitoring, and/or diagnostic evaluation by a health care professional.	The APK 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.	SE
Sterility and Shelf-life	Provided non-sterile. No shelf-life	Provided non-sterile. No shelf-life	SE
Single Patient Use	Yes	Yes	SE
Wire Materials	Shielded&Unshielded Copper with PVC or PP Jacket	Polyvinyl Chloride (PVC)	Analysis 3
Connectors	Medical grade PVC and PP over molded connectors with integral relief.	Medical grade PVC and ABS over molded connectors with integral relief.	Analysis 3
Cable Length (Minimum)	10 Centimeters	0.72 Meters	Analysis 2
Cable Length (Maximum)	11 Foot (3.35 Meters)	3.6 Meters	Analysis 2
Patient end termination type	Clip	Clip , snap	Analysis 4
Number of leadwires	3,5,6	Unknown	Analysis 5
Disposable or reusable	Disposable	Disposable	SE

The Subject Device and the Predicate Device are substantially equivalent. The minor differences are:

Analysis (2) The minimum SureLead Cable System (Subject Device) has a shorter minimum cable length and a shorter maximum cable length. These differences are negligible.

Analysis (3) The material of proposed device is different from predicate device. However, the biocompatibility for proposed device has been evaluated and the test result conform with requirements of ISO 10993 standards. Therefore, this difference does not affect substantially equivalence.

Analysis (4) The patient end termination type of proposed device is Clip while that of predicated device is Clip or snap, yet the electric performance and safety for proposed device has been tested per IEC 60601-1 and EC 53 and the test result is acceptable. Therefore, this difference does not affect substantially equivalence.

Analysis (5) The subject device is available in 3, 5 ,6 leadwire type, while the leadwire number for predicate device is unknown and the substantially equivalence cannot be determined. However, the electric performance and safety for proposed device has been tested per IEC 60601-1 and EC 53 and the test result is acceptable. Therefore, this difference does not affect substantially equivalence.

CONCLUSION

The Intended Use and Indications for Use of the SureLead Disposable Cable System (subject device) and the Predicate Device, Cable / Lead-wire (Premarket Notification K170536) are substantially equivalent. The technological characteristics, components and materials used for the Predicate Device and the Subject Device are the same. The Subject Device, SureLead Disposable Cable System is substantially equivalent to the Predicate Device, Cable / Lead-wire (Premarket Notification K170536), a legally marketed device.