Curbell Medical Products, Inc.
Michael Winter
Sr. Director, Quality and Regulatory Affairs
20 Centre Drive
Orchard Park, New York 14127

Re: K182220
Trade/Device Name: Curbell Patient Monitoring Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: August 10, 2018
Received: October 16, 2018

Dear Michael Winter:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K182220

Device Name
Curbell Patient Monitoring Cables

Indications for Use *(Describe)*
Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare 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.

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CURBELL MEDICAL

Special 510(k) Summary

1. Company: Curbell Medical Products, Inc.
   20 Centre Drive
   Orchard Park, NY 14127
   716-667-3377 x419

2. Contact: Michael Winter

2. Date Prepared: October 10, 2018

3. Trade Name: Curbell Patient Monitoring Cables

4. Common Name: Patient Monitoring Cables
   Models: SAC-JAJA-007-000, Length: 6' 7"
   SAC-JAJA-010-000, Length 10'
   SAC-JAJA-025-000, Length: 25'

5. Classification Name: Patient Transducer and Electrode Cable (including connector) (21CFR870.2900, Product Code DSA)

6. Predicate device(s): Primary Predicate: Curbell Patient Monitoring Cables: 510(k) K081762
   Secondary Predicate for Expanded Use (SPO2 Monitoring): Shenzhen Med-link Electronics Tech Co., Ltd. patient cables and lead wires: K120010

7. Device description: Curbell Patient Monitoring Cables comprise cables and lead wires that connect from sensors and/or electrodes to a monitor for the purpose of conducting ECG diagnosis, monitoring, and SPO2 monitoring. As per 21CFR801.109, this device is a prescription device.

8. Intended use: Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.

9. Technological characteristics to predicate device: Curbell Patient Monitoring Cables are substantially equivalent to the primary predicate device, Curbell Medical Products, Inc. (K081762). Additionally, they are substantially equivalent for expanded use (SPO2 Monitoring) to the secondary predicate device, Shenzhen Med-link Electronics Tech Co., Ltd. patient cables and lead wires: (K120010). This logic follows "Multiple Predicates Example 2", page 11, FDA Guidance Document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."

	Proposed Curbell Patients Cables	Current Curbell Patient Cables (Primary Predicate)	Shenzhen Med-link Electronics Tech Co., Ltd. (Secondary Predicate – SPO2 Monitoring)
510(k) Number	K182220	K081762	K120010
Intended use	Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	Curbell patient cables are used to connect electrodes and/or sensors placed at the appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by a healthcare professional.	The Shenzhen Med-link cables and lead wires are intended to be used with ECG, EKG, SPO2 and Invasive Blood Pressure monitoring devices. The patient cables and lead wires are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by health care professional.
Regulation	21CFR870.2900	21CFR870.2900	21CFR870.2900
Product code	DSA	DSA	DSA
Common Name	Patient cables and leadwires	Patient cables and leadwires	Patient cables and leadwires
Proprietary Name	Curbell branded	Curbell branded	NA
Design/Materials	Shielded and unshielded patient leadwires and shielded patient trunk cables with electrode connectors including snap, pinch, or Sure Lock electrode clip. Trunk cable lengths include - 7 to 20ft. Leadwire lengths from 18" to 120". Wire material is comprised of shielded and unshielded copper with PVC or thermoplastic polyurethane jacket.	Shielded and unshielded patient leadwires and shielded patient trunk cables with electrode connectors including snap, pinch, or Sure Lock electrode clip. Trunk cable lengths include - 7 to 20ft. Leadwire lengths from 18" to 120". Wire material is comprised of shielded and unshielded copper with PVC or thermoplastic polyurethane jacket.	ECG and EKG Cables with various connectors (monitor, trunk/lead wire, electrode grabber & snapper). SPO2 adapter cables with various connectors for connect for the OEM Instrument connector of SPO2 monitor and SPO2 probe. Cable is set at various specified standard lengths. Wire material is comprised of shielded and unshielded copper with PVC or thermoplastic polyurethane jacket.

Biocompatibility	Meets ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization, and ISO 10993-10 Irritation.	Meets ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization, and ISO 10993-10 Irritation	Meets ISO 10993-5 Cytotoxicity, ISO 10993-10 Sensitization, and ISO 10993-10 Irritation
Sterility	Non sterile	Non sterile	Non sterile
Electrical performance testing	ANSI/AAMI EC53: 2013	ANSI/AAMI EC53: 1995 (revised 2001)	ANSI/AAMI EC53:1995 (revised 2001)
Electrical Safety testing	ANSI/AAMI EC53: 2013, IEC 60601-1: 2005, 3rd Edition standard – Part 8.5.2.3 Patient Leads	ANSI/AAMI EC53: 1995 (revised 2001)	ANSI/AAMI EC53:1995 (revised 2001), IEC 60601-1:1998;Am1, A2:1995
Connector Retention Force	ANSI/AAMI EC53: 2013	ANSI/AAMI EC53: 1995 (revised 2001)	ANSI/AAMI EC53:1995 (revised 2001)

The proposed Curbell Patient Monitoring Cables have the following similarities to the current Curbell primary predicate device:

- Same indications for use
- Same manufacturing process
- Similar monitor connector and similar yoke connector
- Same fundamental scientific technology

The proposed Curbell Patient Monitoring Cables have the following similarities to the Shenzhen Med-link secondary predicate device:

- Same intended use (patient monitoring).
- Included indication for use (SPO2 monitoring)
- Similar/equivalent construction
- Same fundamental scientific technology

The proposed Curbell Patient Monitoring Cables have the following differences to the current Curbell primary predicate device:

- Expanded Intended Use (SPO2 monitoring)

The proposed Curbell Patient Monitoring Cables have the following differences to the Shenzhen Med-link secondary predicate device:

- Color
- Length variations

Curbell Reports that provide data and analysis to support the claims provided within:

- Engineering Verification and Validation Protocols
  - **Med-link device** (secondary predicate)

- ANSI/AAMI EC53:2013
    - 5.3.2 - Cable and Lead Wire Noise
    - 5.3.3 - Flex Life of Trunk Cable Flex Relief
    - 5.3.4 - Tensile Strength of Cable Connections
    - 5.3.5 - Number of Connector Mating/Unmating Cycles
    - 5.3.6 - Connector Retention Force
    - 5.3.7 - Contact Resistance
    - 5.3.9 - Dielectric Withstand Voltage
- IEC 60601-1:2005 3rd Edition standard
    - Part 8.5.2.3 Patient Leads
- Cable Mate
- Aux Device Compatibility
- Cable Flex Life

- **Proposed Curbell device**
- ANSI/AAMI EC53:2013
    - 5.3.2 - Cable and Lead Wire Noise
    - 5.3.3 - Flex Life of Trunk Cable Flex Relief
    - 5.3.4 - Tensile Strength of Cable Connections
    - 5.3.5 - Number of Connector Mating/Unmating Cycles
    - 5.3.6 - Connector Retention Force
    - 5.3.7 - Contact Resistance
    - 5.3.9 - Dielectric Withstand Voltage
- IEC 60601-1:2005 3rd Edition standard
    - Part 8.5.2.3 Patient Leads
- Cable Mate
- Aux Device Compatibility
- Cable Flex Life

- **Current Curbell device** (primary predicate)
- ANSI/AAMI EC53:2013
    - 5.3.2 - Cable and Lead Wire Noise

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    - 5.3.3 - Flex Life of Trunk Cable Flex Relief
    - 5.3.4 - Tensile Strength of Cable Connections
    - 5.3.5 - Number of Connector Mating/Unmating Cycles
    - 5.3.6 - Connector Retention Force
    - 5.3.7 - Contact Resistance
    - 5.3.9 - Dielectric Withstand Voltage
  - IEC 60601-1:2005 3rd Edition standard
    - Part 8.5.2.3 Patient Leads
  - Cable Mate
  - Aux Device Compatibility
  - Cable Flex Life

- Engineering Part Evaluation
  - **Proposed Curbell device**
  - Verification of inspection to revision controlled drawings
- Inspection Report
  - **Proposed Curbell device**
  - Dimensional inspection
- Biocompatibility (ISO 10993)
  - **Proposed Curbell device**
  - Wire Jacket Biocompatibility
  - Overmold Biocompatibility
  - Connector Biocompatibility
- Curbell Design Inputs document: SPO2 Adapter Cable
- Curbell Risk Analysis document: SPO2 Adapter Cable

10. Nonclinical performance data:

Curbell Patient Monitoring Cables have been assessed to the following performance standards and special controls:

- IEC 60601-1:2005, Section 8.5.2.3 - Patient Leads
- ANSI/AAMI EC53:2013 ECG Trunk Cables and Patient LeadWires

11. Clinical data: Not Applicable

12. Conclusion from nonclinical testing: The summary above illustrates that there are no different questions of safety or effectiveness of the proposed Curbell Patient Monitoring Cables compared to the current Curbell primary predicate device. Additionally, with respect to expanded use (SPO2 monitoring), the proposed Curbell

Patient Monitoring Cables device is substantially equivalent to the Curbell primary predicate device and the Shenzhen Med-link secondary predicate device.