March 29, 2021

Epitel, Inc.
% John Pappan
RA Consultant / Project Management
LeanRAQA
12602 North Summerwind Drive
Marana, Arizona 85658

Re: K203827
Trade/Device Name: REMI
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: December 24, 2020
Received: December 29, 2020

Dear John Pappan:

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,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203827

Device Name
REMI

Indications for Use *(Describe)*
The REMI Platform is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI consists of Epilog disposable Sensors – a single use, single patient, disposable, wearable sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI-Mobile software and REMI-Tablet are intended to receive and transmit data from four Epilog Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software.

REMI does not make any diagnosis or recommendations and is intended only as a physiological signal monitor. Epilog Sensors are intended for use by trained medical professionals in a professional healthcare facility environment.

Epilog Sensors are intended for use with adult and pediatric patients (6+). (Rx only).

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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510(k) Summary

5.1 Applicant/Submitter

Company Name	: Epitel, Inc.
Phone Number	: 801-497-6297
Company Street Address	: 124 S. 400 E.
City	: Salt Lake City
State	: UT
Country	: USA
Zip Code	: 84111

5.2 Contact Person

Full Name	: Mark Lehmkuhle
Job Title	: CEO/CTO
Phone	: 801-497-6297
Email	: lehmkuhle@epitel.com

5.3 Correspondent Information

Full Name	: John Pappan
Job Title	: RA Consultant / Project Management
Phone	: 718-964-3406
Email	: johnp@leanraqa.com

5.4 Date of Preparation

Date of Preparation	: 02/23/2021

5.5 Device Information

Table - 5.1 Device information

Trade Name	REMI
Common or Usual Name	Electroencephalograph.
Classfication Name	21 CFR 882.1400
Regulatory Class	2
Product Code	OMC, GXY

5.6 Predicate Device(s)

Table - 5.2 Predicate Device(s)

Predicate Type	510(k) Number	Name Of Device	Name Of Manufacturer
Predicate Device	K171459	Ceribell Instant EEG Headband	Ceribell, Inc.
Predicate Device	K170363	Ceribell Pocket EEG Device	Ceribell, Inc.
Predicate Device	K183529	AE-120A EEG Head Set	Nihon Kohden Corporation
Reference Device	K191331	Life Sensor Cardiac Monitor	BraveHeart Wireless, Inc.

5.7 Device Description

REMI amplifies the electroencephalogram (EEG) from a patient's scalp. After amplification, the EEG are sent to the REMI-Tablet running the REMI-Mobile Application. REMI-Mobile combines the EEG from four Epilog Sensors and patient information and relays the data to a cloud server running Persyst software. The EEG data is accessible through the Persyst Mobile interface. REMI is designed for use with adult and pediatric patients (6+). The user interface for the REMI-Tablet is an 10" LCD touchscreen display.

The user interface for Epilog Sensors is a single button keypad overmolded in each Sensor. REMI-Tablet power is through A/C adapter as well as limited onboard rechargeable battery. Epilog Sensor power is through a single-use primary coin cell. Using its wireless link, the Epilog Sensors can exchange EEG data and commands with the REMI-Mobile application running on the REMI-Tablet.

REMI has three major components:
1) Epilog-D disposable EEG sensors,
2) REMI-Mobile – mobile OS application designed to run on a medical-grade tablet, acquire EEG data transmitted from Epilog devices along with user-entered patient and device information, and then transmit the EEG data and patient/device information via wireless encrypted WiFi to,
3) REMI-Cloud – A HIPAA-compliant cloud storage and data processing platform where data is processed into a format that a FDA-cleared (K171184) EEG reviewing software called Persyst can use, which will allow remote neurological review.

5.8 Intended Use/Indications for Use

The REMI Platform is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI consists of Epilog disposable Sensors – a single use, single patient, disposable, wearable sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI-Mobile software and REMI-Tablet are intended to receive and transmit data from four Epilog Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software.

REMI does not make any diagnosis or recommendations and is intended only as a physiological signal monitor. Epilog Sensors are intended for use by trained medical professionals in a professional healthcare facility environment.

Epilog Sensors are intended for use with adult and pediatric patients (6+). (Rx only).

5.9 Comparison of Technological Characteristics with Predicate

REMI is substantially equivalent to the Ceribell Pocket EEG device combined with Ceribell Instant EEG Headband and Nihon Kohden AE-120A EEG headset based on the Comparison Summary in the substantial equivalence discussion.

Epilog Sensors use a one-piece conductive-adhesive "sticker" that includes a conductive hydrogel converted with an adhesive similar to the BraveHeart Wireless Life Sensor Cardiac Monitor. While the BraveHeart sensor amplifies the electrocardiogram from the chest and REMI amplifies the electroencephalogram from the scalp, both devices are wearable sensors intended to record biopotentials that are similar in frequency and amplitude to justify comparison.

Epitel is of the opinion that the individual and combined system differences do not change the safety and effectiveness of this device with respect to the proposed pathway. Nor do the risks vary significantly from the predicate devices, and similar reference devices on the market; what risks do exist are similar and mitigated

through user centric design and a risk management based approach to design controls.

Table - 5.3 Comparison Summary

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Classification Regulation	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within headset)	Class II per 21 CFR 882.1400 Electroencephalograph (EEG Device) Class II per 21 CFR 882.1320 (Instant EEG Headband – cutaneous electrodes)	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within headset)	Class II per 21 CFR 870.2910 Radiofrequency physiological signal transmitter and receiver	Same Classification Regulation to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set
Product Code(s)	OMC and GXY	OMC and GXY	OMC	DRG, DRT, DRX	Same Product Codes to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Indications for Use	The REMI Platform is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI consists of Epilog disposable Sensors – a single use, single patient, disposable, wearable sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI-Mobile software and REMI-Tablet are intended to receive and transmit data from four Epilog Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software. REMI does not make any diagnosis or recommendations and is intended only as a physiological signal monitor. Epilog Sensors are intended for use by trained medical professionals in a professional healthcare facility environment. Epilog Sensors are intended for use with adult and pediatric patients (6+). (Rx only).	The Ceribell Pocket EEG (K170363) Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Pocket EEG Device is intended to be used in a professional healthcare facility environment. (Rx only) The Ceribell Instant EEG Headband (K171459) is an electroencephalogram (EEG) electrode array intended for single patient use in the recording of EEGs in patients of 6 years and older. The Instant EEG Headband is intended for prescription use in the home, healthcare facility or clinical research environment. (Rx Only).	The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the previously cleared and validated Nihon Kohden electroencephalograph systems (EEG-1200A series and EEG-9100) to assist in the diagnosis of neurological disorders. The AE-120A EEG Head Set and its associated EEG Software do not provide any diagnostic conclusion or automated alerts of an adverse clinical event about a patient's condition. The device is intended for use by trained medical professionals in a medical facility such as a physician's office, laboratory, or clinic. The device is intended for use on adults (ages 18 and above). (Rx Only).	The Life Sensor Cardiac Monitor (CM) is a wireless monitoring system intended for use by healthcare professionals for monitoring of physiological data within healthcare settings. This includes heart rate and electrocardiography (ECG). Data is transmitted wirelessly from Life Sensor Electrode to an application on iOS device where it is displayed for review by healthcare professionals. The device is intended for use on general care patients 18 years or older and by prescription only. The device is contraindicated for use on critical care patients, patients with active implantable medical devices such as pacemakers, implanted cardioverter defibrillator (ICD), and left ventricular assist devices (LVAD); for use in magnetic resonance (MR) environments; for use during surgical procedures when electro-surgical equipment is optional. The Life Sensor Cardiac Monitor does not detect or diagnose medical conditions.	No significant difference in Indications for Use to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Physiological Signal Acquired	EEG	EEG	EEG	ECG	Same Physiological Signal Acquired to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set
Type of patient contact	Contacts patient scalp	Contacts patient scalp	Contacts patient scalp	Contacts patient chest over the heart	Same type of patient contact to Ceribell Pocket EEG and Nihon Kohden AE-120A EEG Head Set
Electrodes	2 passive gold electrodes using a conductive hydrogel sticker	10 passive Ag/AgCl electrodes	10 passive Ag/AgCl electrodes	2 passive electrodes using a conductive hydrogel sticker	No significant difference in Electrodes to BraveHeart Wireless Life Sensor Cardiac Monitor

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Type of Use	Epilog Disposable is single use, non-sterile, disposable	Electrodes: Single use, nonsterile, disposable. EEG Device: Ceribell Pocket EEG Device is reusable and non-patient contacting. Ceribell Instant EEG headband is single use, patient contacting and disposable.	Electrodes: Single use, non-sterile, disposable EEG Device: AE-120A EEG Head set is reusable and nonpatient contacting. Belts are patient contacting and reusable (they can be cleaned & disinfected but are recommended for single patient use)	Electrodes: Single use, non-sterile, disposable. The Life Sensor Module automatically performs all the processing functions related to capturing the required physiological data from the body and performs encrypted, bi-directional communication to the Life Sensor Application, using Bluetooth Low Energy (BLE), when in range of the Life Sensor Application installed on a paired iOS device.	No significant difference in Type of Use to all predicates
Channel	Up to 10	8	8	1	No significant difference in EEG Channels to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set
Montage	10/20 system – Epilog-Disposable can be placed anywhere in the 10/20 system where each channel represents a bipolar derivation approximation of the 10/20 system	10/20 System - Ceribell Pocket EEG Device and Ceribell Instant EEG Headband approximates a 10/20 montage	10/20 System - AE-120A EEG Head Set approximates the 10/20 montage but may deviate slightly depending on the patient's head shape	Not Applicable	No significant difference in Montage to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Electrical Safety & EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26 IEC 62133	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-27	No significant difference in Electrical Safety & EMC to predicates
Input Dynamic Range	1 mVp-p	Unknown	1 mVp-p	Unknown	No significant difference in Dynamic Range to Nihon Kohden AE-120A EEG Head Set
Input Noise	5 µVp-p	Unknown (presumed to be same as it meets IEC 60601-2-26)	5 µVp-p or less (0.53 to 60 Hz)	Unknown	No significant difference in Input Noise to Nihon Kohden AE-120A EEG Head Set
Transfer of data	Bluetooth 2.4 GHz	Micro-USB cable	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Same Transfer of data to EEG as Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set
Power Source	CR2016 primary lithium (not rechargeable)	Lithium ion batteries – rechargeable with 100-240 V AC power adapter (Device does not work when connected to AC to recharge)	2 AA (LR6) alkaline batteries (not rechargeable)	Lithium Ion (not rechargeable)	No significant difference in Power Source to all predicates

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Data Format	Lay-Dat (Persyst)	Edf	Nihon Kohden original format	Unknown	No significant difference in Data Format to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set. Persyst is compatible with Edf and Nihon Kohden formats
Compatibility	Epilog Disposable works only with REMI App software and tablet	Ceribell Instant EEG Headband works only with Ceribell Pocket EEG Device	Works only with Nihon Kohden specified EEG's: EEG-1200A series (K080546) EEG-9100 (K011204)	The Life Sensor Application, installed on a paired iOS device, interacts with the Life Sensor Firmware and manages the upload, processing, and display of the physiological data transmitted by the Life Sensor Module.	No significant difference in proprietary compatibility with all predicates.
Software	Epilog Disposable uses integrated firmware only for transmitting EEG to REMI App software and tablet	Ceribell Pocket EEG Device comes with EEG Recording Viewer Software	AE-120A EEG Head Set comes with EEG software to be placed on the compatible EEG for interaction with and viewing of EEG data	Unknown	No significant difference in EEG Software format to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Connector	Epilog Disposable uses a USB protocol on a non-standard connector for programming only	Integrated single cable connector in Ceribell Instant EEG Headband to connect to EEG recording device	Single connector of electrodes to AE-120A Head Set	Unknown	No significant difference in Connector interface to Ceribell Pocket EEG Device and Nihon Kohden AE-120A EEG Head Set
Available Sizes and Dimension	Epilog comes in one size: 27 mm x 27 mm x 7 mm	Small (48.4 – 53.6 cm) Medium (53.3 – 56.5 cm) Large (55.5 – 62 cm)	AE-120A EEG Head Set has flexible arms that are adjusted to fit different adult patient head sizes along with adjustments from the belts/ straps (chin)	One Size	Epilog sensor is smaller than predicates but do not raise concerns of safety or effectiveness
Conductive Electrolyte Gel	Conductive electrolyte is in the form of a hydrogel converted in a one-piece adhesive sticker as an accessory to Epilog-Disposable. The sticker is replaceable and onetime use.	Conductive electrolyte gel is included in a packet gel reservoir integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	Conductive electrolyte paste is included in a packet gel reservoir integrated into each electrode. User inserts electrode into the electrode attachment position in Head Set with paste.	Conductive electrolyte is in the form of a hydrogel converted in a one-piece adhesive sticker as an accessory to the Life Sensor Module. The sticker is replaceable and onetime use.	Same Conductive Electrolyte to BraveHeart Wireless Life Sensor Cardiac Monitor

Attributes	**Subject Device** **REMI**	**Predicate Device(s)*** **Ceribell Pocket EEG Device (K170363)** **Ceribell Instant EEG Headband (K171459)** ***Both K170363 and K171459 together is substantially equivalent to REMI**	**Predicate Device** **Nihon Kohden AE-120A EEG Head Set (K183529)**	**Reference Device** **BraveHeart Wireless Life Sensor Cardiac Monitor (K191331)**	**Comments**
Biocompatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-5and ISO-10993-10	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Same Biocompatibility to all predicates

5.10 Performance Data

5.10.1 Non Clinical

REMI was evaluated for electrical safety in accordance with IEC 60601 Medical Electrical Equipment – Part 1: General requirements for safety. The Epilog sensors were also evaluated for electromagnetic compatibility (EMC), including both emissions and immunity. The Epilog sensors were tested according to IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests to demonstrate the EMC characteristics of the devices. The Epilog sensors were also tested to IEC 60601-2-26 - Particular requirements for the safety of electroencephalographs. The Epilog sensors were also tested to FCC/IC Intentional Radiator per FCC Part 15 Radiated Emissions and Class B Conducted Emissions. Compliance was demonstrated for all tests.

Further detail is discussed in the Declaration of Conformity and Summary Reports.

5.11 Biocompatibility Testing

In accordance with ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the Epilog Sensor is considered to be a surface device that contacts only the skin with prolonged duration. The adhesive sticker accessory (Sticker) is the only component of the Epilog Sensor that comes into direct contact with the patient's scalp.
Both the Epilog Sticker and BraveHeart sticker are directly patient contacting whereas the Ceribell Instant EEG headband and Nihon Kohden AE120 Head Set use electrodes that directly contact the scalp while using a conductive electrolytic gel paste.
The tissue contacting components of the Epilog Sticker include an adhesive and crosslinked conductive hydrogel that is substantially equivalent to the adhesive and crosslinked conductive hydrogel used in the BraveHeart sticker. The crosslinked hydrogel in both the Epilog Sticker and BraveHeart sticker creates an electrically-conductive physical barrier between the scalp and sensor electrodes whereas the low-viscosity of the electrically-conductive gel in both the Ceribell Instant EEG headband and Nihon Kohden AE120 Head Set allow direct contact of the electrodes to the scalp.
Both the Epilog Sensor and BraveHeart Wireless Life Sensor use their respective stickers to mechanically hold their sensors to the scalp and chest, respectively. The Ceribell Instant EEG headband and Nihon Kohden AE120 Head Set use mechanical force to hold the headband and headset to the scalp.
Biocompatibility of patient contacting components for all four devices have been verified with similar Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010. Whereas the Ceribell Instant EEG headband was tested for limited (<24 hour) use, the Epilog Sticker and BraveHeart sticker were tested for prolonged (>24 hour but <30 days) use. Therefore, the Epilog Sticker biocompatibility performance is substantially equivalent to both the BraveHeart sticker and Ceribell Instant EEG headband.

5.12 Clinical Testing

The submission does not contain clinical data.

5.13 Conclusion

REMI is substantially equivalent to the Ceribell Pocket EEG device combined with Ceribell Instant EEG Headband and Nihon Kohden AE-120A EEG headset based on the comparison summary in the substantial equivalence discussion.