September 1, 2023

Cortical Dynamics Ltd
% Tim Marjenin
Vice-President
Mcra, LLC.
803 7th Street NW, 3rd floor
Washington, District of Columbia 20001

Re: K213273
Trade/Device Name: Brain Anesthesia Response Monitor (Bar Monitor)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, OMC, GXY
Dated: August 4, 2023
Received: August 4, 2023

Dear Tim Marjenin:

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,

Ting Song -S

for
Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K213273

Device Name
Brain Anesthesia Response Monitor (BAR Monitor)

Indications for Use *(Describe)*
The BAR Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system displays a patient's EEG and Composite Cortical State (CCS), a proprietary computed EEG index related to the effect of certain anesthetic or hypnotic agents. Anesthetic agents include inhalation agents and propofol in combination with opioids.

The BAR Monitor is intended to assist medical professionals monitor adult patients (22 to 65 years of age) in the operating room (OR) and clinical research laboratory.

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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K213273

510(k) Summary

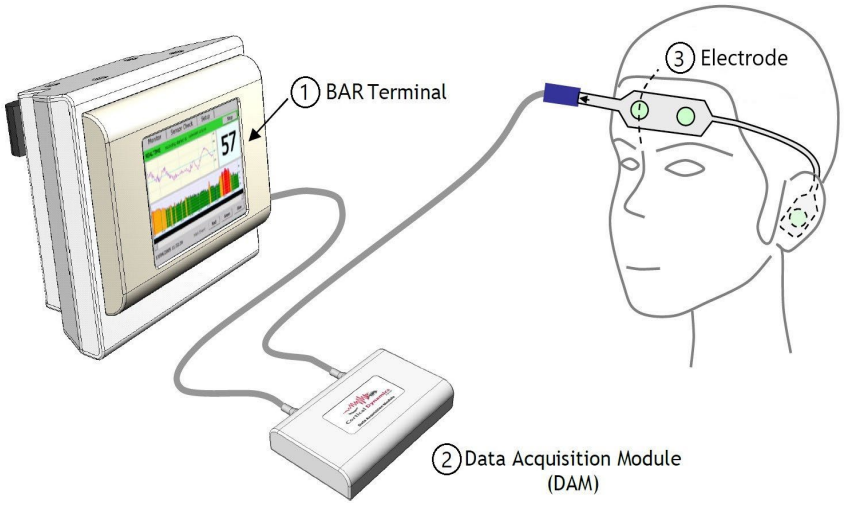
Date	August 4, 2023
Owner/Sponsor	CORTICAL DYNAMICS LTD. 14 View Street North Perth 6006 Western Australia Tel: +61 3 8741 1130
Contact	Tim Marjenin MCRA, LLC 803 7th Street NW, 3rd Floor Washington, DC 20001
Device	Trade Name: Brain Anaesthesia Response Monitor (BARM / BAR Monitor) Common Name: Index-Generating Electroencephalograph Software Classification Name: Electroencephalograph Regulation No: 21 CFR 882.1400 Product Code(s): OLW, OMC, GXY
Classification	Class II
Classification Panel	Neurology
Predicate Device	K072286 - BIS EEG VISTA MONITOR SYSTEM

Device Description

The Brain Anaesthesia Response Monitor (BARM) is a device designed to non-invasively monitor brain function in response to anesthetic agents including inhalation agents in the operating room (OR) and clinical research laboratory. The system consists of the following three components:

- Brain Anaesthesia Response (BAR) Terminal – Provides a user interface to control the DAM, set configuration parameters and display the DAM output for users.
- Data Acquisition Module (DAM) – Collects and processes the signal sent by the electrodes and calculates the Composite Cortical State (CCS) index and outputs the information to the BAR Terminal.
- Disposable cutaneous electrode sensor- The electrodes collect Brain electrical activity (EEG)

signals and transfers them to the DAM. The electrodes are made from pre-gelled Ag-AgCl. The electrodes are connected with patient leads which is plugged into the DAM. The electrodes are applied to the patients' forehead and behind the ear and is held in place via biocompatible adhesives.



Intended Use

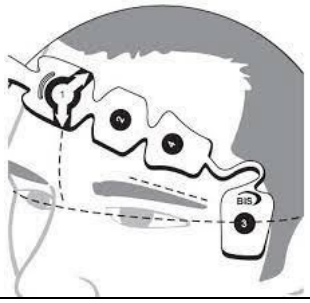
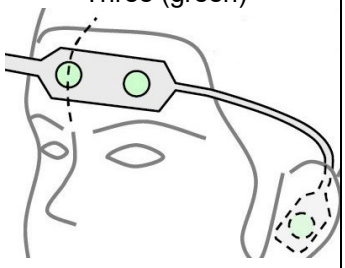
The BAR Monitor is intended to monitor the state of the brain by real- time data acquisition and processing of EEG signals. The system displays a patient's EEG as well as Composite Cortical State (CCS), a proprietary computed EEG index related to the effect of certain anesthetic or hypnotic agents. Anesthetic agents include inhalation agents and propofol in combination with opioids.

The BAR Monitor is intended to assist medical professionals monitor adult patients (22 to 65) in the operating room (OR) and clinical research laboratory.

Comparison Of Technological Characteristics With The Predicate Device

FEATURE	BIS EEG VISTA MONITOR SYSTEM AND BISX	Subject Device	Comparison
510(k) Number	K072286	-	**N/A**
Company	Aspect Medical System Inc.	Cortical Dynamics Ltd.	**N/A**
Regulation	21 CFR 882.1400	21 CFR 882.1400	**Identical**
Class	II	II	**Identical**
Product Code	OLW, OLT, OMC, ORT	OLW, OMC, GXY	**Equivalent**
Indications for Use	The BIS VISTA Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel	The BAR Monitor is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals.	**-**

FEATURE	BIS EEG VISTA MONITOR SYSTEM AND BISX	Subject Device	Comparison
	trained in its proper use. The BIS VISTA Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS™ may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.	The system displays a patient's EEG and Composite Cortical State (CCS), a proprietary computed EEG index related to the effect of certain anesthetic or hypnotic agents. Anesthetic agents include inhalation agents and propofol in combination with opioids. The BAR Monitor is intended to assist medical professionals monitor adult patients (22 to 65) in the operating room (OR) and clinical research laboratory	
EEG Waveforms Amplitude (default)	25 µV/ division	25 µV/ division (Default) Additional sensitivity options of 10 µV, 20 µV, 50 µV, 100 µV, 200 µV which displays signals at 5, 10, 25, 50, 100 µV /division.	**Equivalent**
EEG Chart Speed (default)	30 mm/sec	32mm/sec (Default) Additional options 8 & 16 mm/sec	**Equivalent**
Index calculated related to effect of anesthetic agents	BIS (0 to 100)	CCS (0 to 100)	**Equivalent**
Electromyograph (EMG) Indicator	**30 – 55dB**	Not Available	**Different**
Suppression Ratio (SR)	0 to 100%	SR is incorporated into the Signal Quality measure and not displayed	**Different**
Burst Count	0 - 20/min	Parameter not calculated nor displayed	**Different**
Signal Quality Indicator (SQI)	0-100 (20 points per bar)	0 - 100%. Displayed on trend chart when less than 100%	**Different**
Electrode Impedance	Parameter displayed as Pass, High, Noise, or Lead Off. Unknown range.	Parameter not displayed	**Different**
Index calculated related to effect of anesthetic agents	1 (BIS)	1 (CCS)	**Equivalent**
Storage / recording	The duration of	BARM has data and trend storage space for > 1000	**Equivalent**

FEATURE	BIS EEG VISTA MONITOR SYSTEM AND BISX	Subject Device	Comparison
	trend data stored is approximately 72 hours. The duration of BISx data (processed EEG parameters, including the BIS value, with time and date of acquisition) stored is approximately 1200 hours.	hours	
AC Power	100-240 VAC, 50-60 Hz 24 W	100~240VAC, 50-60Hz, 30W	**Equivalent**
Rechargeable battery	A rechargeable lithium-ion battery inside the monitor provides approximately 45 minutes of back-up power when power cannot be supplied via the power cord.	BARM contains backup battery with > 1 hour runtime	**Equivalent**
Module Connection	BISX interfaces with BIS VISTA Monitoring system	DAM interfaces with BARM Terminal	**Equivalent**
Module: Dimensions	2.6 in x 1.00 in x 4.25 in (6.6 cm x 2.5 cm x 10.8 cm)	DAM: 155x123x28mm (6.10x4.84x1.10 in)	**Equivalent**
Operating Temperature	0°C to +40°C 32°F to 104°F	0°C to +40°C 32°F to 104°F	**Equivalent**
Operating Humidity	15% to 95% (non-condensing)	10% to 95% @ +40°C non-condensing	**Equivalent**
Transport and Storage Environment			
Temperature	-10°C to +60°C 14°F to 140°F	-20°C to +60°C -4°F to +140°F	**Equivalent**
Humidity	15% to 95% (non-condensing)	10% to 95% @ +40°C non-condensing	**Equivalent**
Pressure	48 kPa to 106.7 kPa	70kPa to 106 kPa	**Equivalent**
Cutaneous Electrode			
Product code	GXY	GXY	**Equivalent**
Where used	Head	Head	**Equivalent**
Material	Pre-gelled silver/silver chloride electrode array	Pre-gelled Ag-AgCl electrodes	**Equivalent**
Quantity	Four 	Three (green) 	**Different**

FEATURE	BIS EEG VISTA MONITOR SYSTEM AND BISX	Subject Device	Comparison
Number of cables	Single Cable	Single Cable	**Equivalent**
Single Use or Re-useable	Single-Use	Single-Use	**Equivalent**
Sterile or non-sterile	Non-sterile	Non-sterile	**Equivalent**
Analog Noise	< 0.3 µV RMS (2.0 µV peak-to-peak); 0.25 Hz to 50 Hz	< 0.4µV (RMS). < 1.25 µV (peak to peak)	**Equivalent**
A/D	16 bit	16 bit	**Equivalent**
CMR	110 dB	> 108 dB	**Equivalent**
Bandwidth	0.16 – 450 Hz	0.5 – 200 Hz	**Equivalent**
Sampling Frequency	256 Hz	480 Hz	**Different**
Sampling Rate	16,384 samples/second	100,000 samples/second	**Different**
Unprocessed EEG available	Yes	Yes	**Equivalent**
Display	4” x %.25” Colour Touchscreen	4” x 5.5” Colour Touchscreen	**Equivalent**
Algorithm Output	The Bispectral Index (BIS) is the output from a multivariate discriminate analysis that quantifies the overall bispectral properties (frequency, power, and phase)throughout the entire frequency range.	Composite Cortical State (CCS) is derived from the patients EEG using the linearised Liley model of EEG genesis. CCS is derived every second from the patients EEG after automatic removal of data materially contaminated by diathermy or artifacts	**Equivalent**
Display of EEG time series	Yes	Yes	**Equivalent**
Displays Depth of Anesthesia index value and trend graph	BIS	CCS	**Equivalent**
Burst Suppression	Suppression is quantified as a Suppression Ratio (SR). SR is displayed and is not incorporated into signal quality measure	Burst suppression is incorporated in signal quality measure	**Different**
Medical device safety and EMC/EMI certificates	UL 60601-1, IEC 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1 IEC 60601-1-2:2001	IEC60601-1:2005 IEC60601-1:2005/AMD1:2012 IEC60601-1-6:2010 IEC60601-1-6: 2010/AMD1:2013 IEC60601-2-26:2016 IEC60601-1-2:2007 3rd Ed	**Equivalent**

Non-clinical Performance Testing

The following non-clinical testing was conducted:

- Battery Safety Testing per IEC 62133
- Electrical and Environmental Safety Testing per IEC 60601-1
- Electrical Safety and Essential Performance Testing per IEC 60601-2-26
- EMC Testing per IEC 60601-1-2
- Risk Assessment per ISO 14971
- Software Verification and Validation per FDA Software Guidance
- Usability Evaluation per IEC 60601-1-6 and IEC 62366-1
- Biocompatibility testing per ISO 10993-1

Per the completed testing the requirements and performance specifications for the subject device were met, including compliance with the requirements for electro-encephalographic medical devices and is as safe and effective for brain function monitoring in clinical settings.

Clinical Performance Data

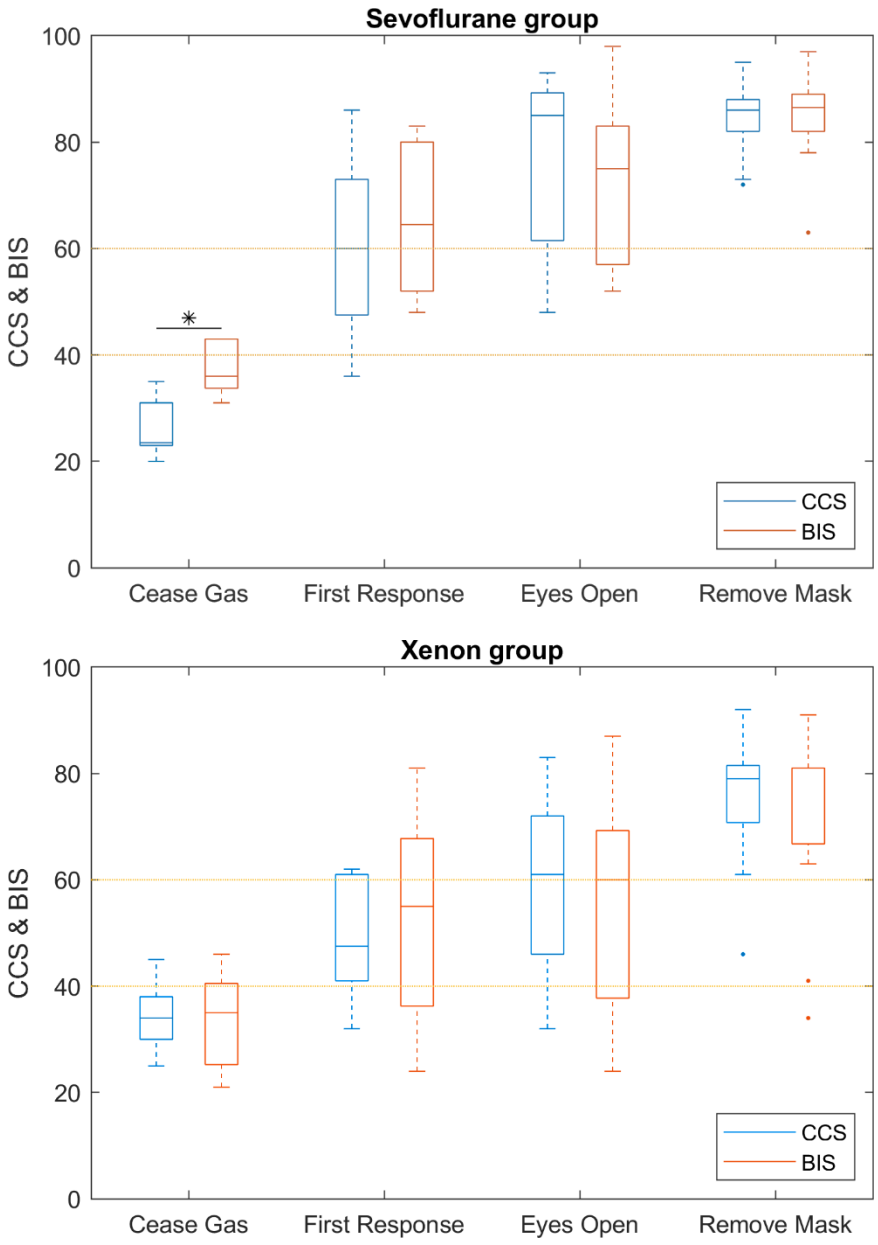
Study U1111-1124-2523

The U1111-1124-2523 study was a double-blinded, randomized controlled design conducted in Melbourne, Australia with 20 subjects undergoing cardiac surgery. BARM was used to monitor anesthetic induction using propofol, fentanyl and benzodiazepines. Subjects were pre-sedated with lorazepam and midazolam to an Observer's Assessment of Alertness/Sedation (OAA/S) level 4 (lethargic response to name spoken). Subjects then received a 1mg/kg bolus of propofol followed by an infusion at 6mg/kg/hr until loss of response to verbal command and painful stimulus (OAA/S 0). Subjects then received either a low (FLD, 8µg/kg) or moderate dose (FMD, 16µg/kg) of fentanyl. CCS was observed to decrease from OAA/S 4 (FLD: 73, FMD: 79) to OAAS/0 (FLD: 57, FMD: 58). CCS was found to be equivalently predictive of loss of response as the BIS™ index, based on prediction probability ($P_{k,}$ 0.9 for both devices). P_k has a value of 1 when the indicator variable (e.g., CCS, BIS) predicts observed anesthetic depth perfectly and a value of 0.5 when the indicator predicts no better than a 50:50 chance.

Study ACTRN12618000916246

The ACTRN12618000916246 study was a double-blinded, randomized controlled design in conducted in Melbourne, Australia with 21 patients. BARM was used to monitor emergence from sevoflurane (10 subjects) and xenon (11 subjects) anesthesia with remifentanil (0.1µg/kg/min). Anesthesia was maintained at 90% of the minimum alveolar concentration (MAC) equivalent of the respective agents while a lithotripsy procedure was performed. After the procedure was complete all anesthetic agents were ceased and the subject monitored every 30s for signs of emergence, including first response to name, first eyes open and spontaneously ventilating sufficient to remove the laryngeal mask. CCS was observed to increase from the cessation of anesthetic and across the signs of emergence, with comparable values to the BIS™ index. CCS and BIS values were only significantly different at cease gas in the sevoflurane group, but without a ground truth assessment at cease gas, it is unclear whether CCS or BIS more accurately reflects actual patient state. BIS and CCS values were lower at emergence endpoints for xenon than for

sevoflurane. This effect has been previously reported for the BIS. Prediction probabilities calculated across the emergence endpoints for CCS were equivalent to or better than that for the BIS for the sevoflurane group, the xenon group and both groups combined.



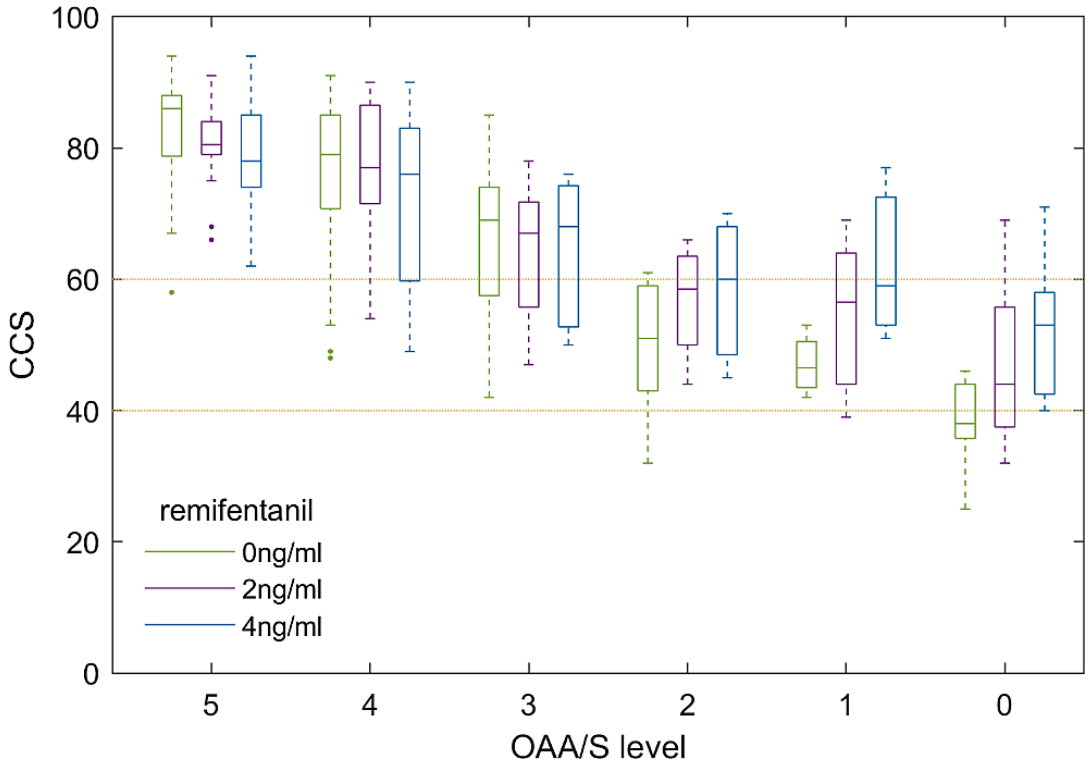
CCS and BIS values at clinical endpoints and cessation of gas for sevoflurane and xenon groups. * p < 0.05 (Wilcoxon sign rank test)

Study 6001-004

The BARM algorithms have also been investigated by re-analysing previously recorded EEG data. In one randomized, multi-arm study in Belgium, anesthesia was induced by progressively

increasing the effect-site concentration of propofol (0.75µg/ml starting dose, 0.25µg/ml increments every 4 minutes). Subjects were also co-administered either 0, 2 or 4ng/ml remifentanil (14 subjects per group, 42 total subjects). OAA/S assessments were performed before each increase in propofol dose. CCS was observed to decrease with decreasing OAA/S level - OAA/S 5 (awake) median CCS: 86 (0ng/ml group), 80 (2ng/ml group), 78 (4ng/ml group); OAA/S 0 (unresponsive) median CCS: 38 (0ng/ml), 44 (2ng/ml), 53ng/ml (4ng/ml).

These findings support a recommended range of CCS>80 corresponding to awake and CCS between 40-60 corresponding to unresponsive. CCS varies comparably to other depth of anesthesia indices. Prediction probabilities calculated across all OAA/S levels were 0.85, 0.84, 0.78, and 0.83 (0, 2, 4ng/ml and all combined respectively), equivalent to values obtained using GE M-Entropy™ state and response entropy measures. Prediction probabilities between OAA/S 5 and OAA/S 0 were ≥0.99 indicating near perfect discrimination, CCS is also highly predictive of response to vocal stimulus (P_k ³ 0.86). Across all OAA/S levels, CCS has comparable prediction probabilities to the State and Response Entropy indexes of the M-Entropy monitor.



Box and whisker plots for CCS vs OAA/S level for each remifentanil group

Conclusion

Evaluation of the risks and performance data based on the differences between the subject and predicate devices does not raise any new issues or concerns related to safety or effectiveness. Cortical Dynamics has concluded that the BARM device is as safe and effective as the predicate device for its intended use and is substantially equivalent to the predicate device.