July 18, 2024

Braincare Desenvolvimento e Inovação Tecnológica S.A.
% Cherita James
Official Correspondent
ProPharma MedTech
1129 20th Street NW, Ste 600
Washington, District of Columbia 20036

Re: K240821
Trade/Device Name: B4C System with BcSs-PICNIW-2000 sensor model
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: March 21, 2024
Received: March 25, 2024

Dear Cherita James:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Patrick Antkowiak -S

for
Jay Gupta, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240821

Device Name

B4C System - Addition of new sensor model (BcSs-PICNIW-2000)

Indications for Use *(Describe)*

The B4C System is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in intracranial compliance, by providing surrogate ICP waveforms and associated parameters (estimated P2/P1 ratio, normalized Time-to-Peak, derived useful ICP pulses and cardiac pulses) for interpretation.

Refer to device labeling for more information regarding the derivation and interpretation of the output of the device.

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.

510(k) Summary

B4C System – Addition of BcSs-PICNIW-2000 Sensor

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Date Prepared: March 6, 2024

Proprietary Name: B4C System (Addition of BcSs-PICNIW-2000 Sensor)

Common Name: Intracranial pressure monitoring device

Regulatory Class: II

Regulation: 882.1620

Product Code: GWM

Predicate Device(s): B4C System K201989

Device Description

The B4C System is a non-invasive device intended for monitoring of variation in intracranial pressure including patients with suspected alteration of intracranial pressure (ICP) or change in intracranial compliance. It consists of a sensor with Bluetooth wireless module, headband, mobile device software application, receiver, charger, as well as processing and analytical software. The subject of this 510(k) is to introduce an additional sensor, model BcSs-PICNIW-2000, that is compatible with the existing B4C System (K201989). The BcSs-PICNIW-2000 sensor consists of a piezoelectric fixed on a circular base that is supported on a headband placed over the patient's head. The skull pulsation is sensed by the fixed piezoelectric. Users may use either the existing sensor or the new sensor with the B4C System. During monitoring sessions, either sensor continuously transmits the signal to the Mobile App via Bluetooth connection and then to the analytical software component, Physio Core, to perform signal processing. The processed information is then sent back to the Mobile App in the form of minute by minute graphs of waveform derived parameters as well as a report with additional waveform information. Like the predicate

sensor, the proposed sensor does not measure absolute intracranial pressure values, but continues to produce surrogate waveform morphology, its trend, and associated parameters reflecting changes in ICP. The B4C System and surrogate waveform and associated outputs do not substitute ICP monitoring methods when measurement of the absolute value of ICP is required to make a clinical decision.

The sensor is supported on a headband worn by the patient, such that the sensor is in contact with the scalp and is perpendicularly positioned in the temporoparietal transition, 2 inches (5-6 cm) above the entrance of the external auditory canal on the coronal plane. Slight pressure is applied so that the sensor maintains contact with the scalp throughout the monitoring session. The sensor continuously records and transfers acquired data to the B4C analytical and processing software, and back to the mobile device application or to a compatible multi-parameter monitor that has piezoresistive pressure transducer sensitivities of 5μV/Vex/mmHg or greater and automatic amplitude window adjustment capability via a paired receiver. Data is transferred wirelessly via Bluetooth connection between sensor and mobile application and HTTPS protocol between mobile application and analytics software. The clinician may view the visualized waveform on the mobile device along with real-time waveform, minute by minute graphs, intermediate, or final reports of surrogate waveform and associated parameters including surrogate waveform trend line, average waveform per minute and estimated P2/P1 ratio, normalized time to peak, as well as derived useful ICP pulses and cardiac pulses. Alternatively, with a supplied dongle, a paired patient monitor's inherent software interprets the signal received from the B4C System's sensor and displays a surrogate waveform that allows for viewing the same ICP waveform on the monitor's display. Clinicians review the B4C System outputs to assess patients with suspected intracranial hypertension or changes in intracranial compliance based on the characteristics Percussion (P1), Tidal (P2,), and Dicrotic (P3) peaks of the waveform morphology and associated parameters.

The B4C System is not intended to be a standalone diagnostic tool. The surrogate waveform and associated parameter outputs do not replace a comprehensive clinical evaluation, but only provide an element for preliminary assessment. The clinician is responsible for determining the additional clinical information that may be required to make a diagnosis.

The B4C System is intended for use for adult patients ages 18 and older.

Indications for Use: The B4C System is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in intracranial compliance, by

providing surrogate ICP waveforms and associated parameters (estimated P2/P1 ratio, normalized Time-to-Peak, derived useful ICP pulses and cardiac pulses) for interpretation.

Refer to device labeling for more information regarding the derivation and interpretation of the output of the device.

Comparison to Predicate Device

The subject of this 510(k) is to introduce the additional BcSs-PICNIW-2000 sensor to the existing B4C System that is marketed under K201989. A comparison of the subject and predicate devices is presented in **Table 1**. The differences compared to the currently marketed device do not affect the intended use and do not raise new questions of safety and effectiveness.

Table 1 Comparison of Subject and Predicate Devices

	B4C System Addition of Sensor BcSs-PICNIW-2000	**B4C System K201989**	**Substantial Equivalence**
Product Code	GWM	GWM	Same
Indications for Use	The B4C System is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in intracranial compliance, by providing surrogate ICP waveforms and associated parameters (estimated P2/P1 ratio, normalized Time-to-Peak, derived useful ICP pulses and cardiac pulse) for interpretation. Refer to device labeling for more information regarding the derivation and interpretation of the output of the device.	The B4C System is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in intracranial compliance, by providing surrogate ICP waveforms and associated parameters (estimated P2/P1 ratio, normalized Time-to-Peak, derived useful ICP pulses and cardiac pulse) for interpretation. Refer to device labeling for more information regarding the derivation and interpretation of the output of the device.	Same
Prescription Device	Yes	Yes	Same
Device Description	Non-invasive ICP monitoring device consisting of pressure sensors supported on a headband to detect skull	Non-invasive ICP monitoring device consisting of strain gauge pressure sensors supported on a headband to detect skull deformations in	Similar. The main difference compared to the predicate is that an additional sensor is introduced as an option

	deformations in response to ICP changes. System wirelessly transmits acquired signal for processing and analytics. System outputs surrogate ICP waveform and report of waveform's associated parameters on mobile device application and web portal. ICP waveform may also be viewed on compatible monitor via paired wireless receiver. This 510(k) introduces an additional piezoelectric pressure sensor available for use with the existing B4C System in addition to a strain gauge pressure sensor.	response to ICP changes. System wirelessly transmits acquired signal for processing and analytics. System outputs surrogate ICP waveform and report of waveform's associated parameters on mobile device application and web portal. ICP waveform may also be viewed on compatible monitor via paired wireless receiver.	to the user with the existing B4C System. The B4C System's software components have also undergone minor software updates.
Clinical Application	Non-invasive application of a sensor on the scalp perpendicularly positioned in the temporoparietal transition, 2 inches (5-6 cm) above the entrance of the external auditory canal on the coronal plane	Non-invasive application of a sensor on the scalp perpendicularly positioned in the temporoparietal transition, 2 inches (5-6 cm) above the entrance of the external auditory canal on the coronal plane	Same
Contraindications	The B4C System is contraindicated for use in patients who have: ● Undergone decompressive craniectomy or craniotomy; ● Cranial defects (portion of skull missing); Any other conditions that the health practitioner deems to be unsuitable for use of this device.	The B4C System is contraindicated for use in patients who have: ● Undergone decompressive craniectomy or craniotomy; ● Cranial defects (portion of skull missing); Any other conditions that the health practitioner deems to be unsuitable for use of this device.	Same
Device Materials	● Silicone and polycarbonate/ABS sensor casing ● Polypropylene headband	● Polycarbonate sensor casing and contact pin ● Silicone base around sensor ● Polypropylene headband	Same materials
MRI Claim	MR Unsafe	MR Unsafe	Same

Sterilization	Not applicable	Not applicable	Same
Device dimensions	Sensor case: 250 x 40 x 34 mm Receiver case: 94 x 17.5 x 15 mm Headband size with turnbuckle: 340 x 32 x 20 mm (smallest) 460 x 32 x 20 mm (largest)	Sensor case: 75.6 X 51.5 X 27.7 mm Receiver case: 94 X 17.5 X 15 mm Receiver cable and connector length: 20 cm Headband size with turnbuckle : XXS: 49.5 cm, XS: 52 cm, S: 54.5 cm, M: 57 cm, L: 59.5 cm, XL: 52 cm, XXL: 64.5 cm	Similar. Differences in dimensions do not raise new questions of safety or effectiveness.
Biocompatibility	Limited duration contact (≤24) with intact skin Non-cytotoxic Non-sensitizing Non-irritating	Limited duration contact (≤24) with intact skin Non-cytotoxic Non-sensitizing Non-irritating	Same
Energy modality	Sensor contains internal rechargeable battery	Sensor contains internal rechargeable battery and external rechargeable battery pack	Similar Both subject and predicate sensors contain internal rechargeable batteries. The subject sensor does not include an external rechargeable battery pack. This difference does not raise new questions of safety and effectiveness.
ICP Waveform Outputs	Waveform displayed on compatible patient monitor Analytical software also produces the following associated parameters about the surrogate ICP waveform displayed in a report and on the accompanying mobile medical application: ● Surrogate Waveform ● Waveform Trend line ● Average waveform ● Estimated P2:P1 ratio	Waveform displayed on compatible patient monitor Analytical software also produces the following associated parameters about the surrogate ICP waveform displayed in a report and on the accompanying mobile medical application: ● Surrogate Waveform ● Waveform Trend line ● Average waveform ● Estimated P2:P1 ratio ● Normalized Time-to-Peak ● Derived useful ICP	Same

	● Normalized Time-to-Peak ● Derived useful ICP pulses ● Derived Cardiac Pulse These associated parameters are derived based on well-established principles in scientific literature and clinical practice.	pulses ● Derived Cardiac Pulse These associated parameters are derived based on well-established principles in scientific literature and clinical practice.	
Sensing element	Piezoelectric	Strain gauge	Different The subject sensor utilizes a piezoelectric while the predicate sensor is strain gauge based. Both sensors follow the same operating principle of detecting changes in ICP through small variations in skull deformation based on well-understood principles of ICP waveform morphology. Performance data demonstrate that this difference does not raise new questions of safety and effectiveness.
Functional pressure range	Not applicable as it does not provide absolute values of pressure	Not applicable as it does not provide absolute values of pressure	Same
Functional over pressure range without damage	Not applicable as it does not provide absolute values of pressure, and does not have a specified functional pressure range.	Not applicable as it does not provide absolute values of pressure, and does not have a specified functional pressure range.	Same
Input/ Output Impedance	The wireless sensor is not physically connected to any device and has an internal resistive bridge of 3000 Ohms (typical values). It also uses a piezoeletric disc that does not require a power supply to generate electric charges, with typical capacitance in the	The wireless sensor is not physically connected to any device and has an internal resistive bridge with input and output impedance of 1000 Ohms.	Similar. Differences do not raise new questions of safety and effectiveness.

	magnitude of 14.5 nF.		
Output signal (sensitivity)	Not applicable for the wireless sensor since it is not physically connected to any device. The receiver can output a maximum signal of 25mV and minimum of -2.5mV.	Not applicable for the wireless sensor since it is not physically connected to any device. The receiver can output a maximum signal of 25mV and minimum of -2.5mV.	Same
Zero Drift	Not applicable for the sensor as it does not provide absolute values and brain4care App performs auto scale so that the waveform is always visible. The receiver is also capable of automatically readjusting the signal offset level so that the waveform is always visible on the monitor.	Not applicable for the sensor as it does not provide absolute values and brain4care App performs auto scale so that the waveform is always visible. The receiver is also capable of automatically readjusting the signal offset level so that the waveform is always visible on the monitor.	Same
Electrical Safety	Complies with IEC 60601-1	Complies with IEC 60601-1	Same
Electromagnetic Compatibility	Complies with IEC 60601-1-2	Complies with IEC 60601-1-2	Same
Software	The B4C System includes a mobile device application, firmware, analytical and processing software, and administrative software components.	The B4C System includes a mobile device application, firmware, analytical and processing software, and administrative software components.	Same
Sensor Connection to Monitor	Wireless Bluetooth connection to a receiver or micro-USB connection specific to compatible patient monitors	Wireless Bluetooth connection to a receiver or micro-USB connection specific to compatible patient monitors	Same
Wireless Module	Bluetooth	Bluetooth	Same

Differences from Predicate

This 510(k) introduces the addition of the BcSs-PICNIW-2000 sensor to the existing B4C System, the predicate device K201989. The main difference is an additional sensor that uses a piezoelectric based sensor compared to the existing strain gauge based sensor. The B4C System continues to maintain the same indications for use, operating principle of detecting small variations in skull deformation, and clinical utility. There are no significant changes to the B4C System software.

Discussion of Performance Data

The following performance data in **Table 2** are provided in support of demonstrating substantial

equivalence between the subject and predicate devices.

Table 2 Summary of Non-Clinical Performance Data

TEST	TITLE/TEST METHOD SUMMARY	RESULTS
Biocompatibility		
The BcSs-PICNIW-2000 is comprised of the same materials as the predicate device sensor. A biological risk assessment was provided in lieu of repeating testing.		
Electrical Safety and Electromagnetic Compatibility		
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
ANSI AAMI ES 60601-1		Pass
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral	Pass
AAMI TIR69	Risk management of radio-frequency wireless coexistence for medical devices and systems	Testing not required based on risk assessment
Disinfection		
The BcSs-PICNIW-2000 is intended to be reprocessed according to the same methods as the predicate device sensor. Reprocessing validation was not required.		
Bench Testing		
Monitor Compatibility	There are no changes to the predicate device receiver and wireless communication protocol. Monitor compatibility testing was not repeated.	
Stability and Reproducibility	Demonstration of stability, repeatability, and reproducibility between the ICP waveform outputs of the wireless and wired sensors.	Pass
Software		
Software Verification and Validation	Demonstrate that all software requirements were appropriately implemented in the software.	Pass

Non-clinical performance data is sufficient to demonstrate substantial equivalence.

Conclusion

Based on results of the performance testing and substantial equivalence comparison, the B4C System maintains the same intended use as the predicate device and the information presented is sufficient to determine that the subject device is substantially equivalent to the predicate device.