October 17, 2019

Braincare desenvolvimento e Inovacao Tecnologica S.A.
% Ms. Connie Qiu
Regulatory Consultant
M Squared Associates, Inc.
575 8th Ave, Suite 1212
New York, New York 10018

Re: K182073
Trade/Device Name: BcSs-PICNI-2000 Sensor
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial Pressure Monitoring Device
Regulatory Class: Class II
Product Code: GWM
Dated: September 16, 2019
Received: September 17, 2019

Dear Ms. Connie Qiu:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182073

Device Name
BcSs-PICNI-2000 Sensor

Indications for Use *(Describe)*
The BcSs-PICNI-2000 Sensor is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in brain compliance, by providing ICP waveforms for interpretation.

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

BcSs-PICNI-2000 Sensor

Sponsor: Braincare desenvolvimento e Inovacao Tecnologica S.A.
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Date Prepared: September 16, 2019

Proprietary Name: BcSs-PICNI-2000 Sensor

Common Name: Intracranial pressure monitoring device

Regulatory Class: II

Regulation: 882.1620

Product Code: GWM

Predicate Device: Codman® Microsensor Basic Kit K153347

Reference Device: BrainPulse, Model 1100 DEN140040

Device Description

The BcSs-PICNI-2000 Sensor ("the Braincare Sensor") is a non-invasive device intended for the monitoring of variation in intracranial pressure, including patients with suspected alteration of intracranial pressure (ICP) or change in brain compliance. It consists of a sensor, headband, and adapter cable. The sensor contains four strain gauges situated on a metal bar that detects variations in skull deformation through tension and compression of the metal bar in response to changes in intracranial pressure. The proposed device does not measure absolute intracranial pressure values, but produces waveform morphology and its trend reflecting changes in ICP. The BcSs-PICNI-2000 Sensor and waveform output do not substitute ICP monitoring methods when measurement of the absolute value of ICP is required to make a clinical decision.

The sensor component is supported on a plastic 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 pin maintains contact with the scalp throughout the monitoring session. The sensor continuously records and transfers acquired signals through an adapter cable to a compatible multi-parameter monitor that has piezoresistive pressure transducer sensitivities of 5µV/Vex/mmHg or greater and automatic amplitude window adjustment capability. The multi-parameter monitor's inherent software interprets the signal received from the BcSs-PICNI-2000 Sensor and displays a waveform that allows for assessment of suspected intracranial hypertension or changes in brain compliance based on the characteristic Percussion (P1), Tidal (P2), and Dicrotic (P3) peaks of the ICP waveform morphology.

The BcSs-PICNI-2000 Sensor is not intended to be a standalone diagnostic tool. The waveform output does not replace a comprehensive clinical evaluation, but only provides an element for preliminary assessment. The clinician is responsible for determining the additional clinical information that may be required to make a diagnosis.

Intended Use: The BcSs-PICNI-2000 Sensor is intended for the monitoring of variation in intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in brain compliance, by providing ICP waveforms for interpretation.

Comparison to Predicate Device

Comparison of technological characteristics between the BcSs-PICNI-2000 Sensor to the predicate device, Codman® Microsensor Basic Kit (K153347), is presented in **Table 1**. The differences between the two devices do not affect the intended use, and do not raise new questions of safety and effectiveness.

Table 1 Comparison of BcSs-PICNI-2000 Sensor to Codman® Microsensor Basic Kit

	Braincare BcSs-PICNI-2000 Sensor	**Codman Microsensor Basic Kit Refs. 62-6631**	**Substantial Equivalence**
510k #	K182073	K153347	Not applicable
Product Code	GWM	GWM	All devices are Intracranial Pressure Monitoring devices.
Indication for Use	The BcSs-PICNI-2000 Sensor is intended for the monitoring of variation in	Use of the CODMAN MICROSENSOR	Both the BcSs-PICNI-2000 Sensor and the Codman ®

	intracranial pressure in patients with suspected alteration of intracranial pressure (ICP) or change in brain compliance, by providing ICP waveforms for interpretation.	Basic Kit is indicated when direct ICP monitoring is required. The kit is indicated for use in both subdural and intraparenchymal pressure monitoring applications only.	Microsensor are intended for ICP monitoring. Comparable performance of the non-invasive Braincare Sensor and the Codman® Microsensor has been confirmed in clinical and animal testing.
Prescription device	Yes	Yes	Both devices are intended for prescription use only.
Device Description	Non-invasive ICP monitoring device consisting of strain gauge pressure sensors supported on a headband to detect skull deformations in response to ICP changes.	ICP Transducer consist of a miniature strain gauge pressure sensor mounted in a titanium case at the tip of a 100cm 3 french flexible nylon tube.	Both devices utilize strain gauge sensors and are used in real-time ICP monitoring.
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	Subdural and intraparenchymal implantation.	Braincare Sensor is applied non-invasively, while the Codman® Microsensor requires subdural and intraparenchymal implantation. Both devices share the same intended use, and have satisfied biocompatibility and performance testing. The potential differences for patient application is restricted to the non-invasiveness nature of the BcSs-PICNI-2000 Sensor, which is similar to the Reference Device; therefore it does not raise new questions in terms of safety and effectiveness.
Contraindications	The BcSs-PICNI-2000 Sensor is contraindicated for use in patients who have: • Undergone decompressive craniectomy or craniotomy;	This kit is not designed, sold or intended for any use except as indicated. This kit is not designed, sold or intended for use as a therapeutic device.	Both the subject and predicate devices are designed and intended only for the use as indicated. The Braincare device carries additional contraindications specific to its use as a non-invasive ICP monitoring device.

	• Cranial defects (portion of skull missing); • Any other conditions that the health practitioner deems to be unsuitable for use of this device.		However, these additional contraindications do not introduce new risks compared to the predicate device. The difference in contraindications do not raise new questions in terms of safety and effectiveness.
Device Materials	• Polyoxymethylene sensor and headband. • Adapter cable: TPU (thermoplastic polyurethane) and ABS (Acrylonitrile butadiene styrene) case.	• PCB in plastic connector housing, solder wire, • resistor in plastic housing, • epoxy glue • Silicone Catheter strain relief • Ti case • Silicone membrane	The Braincare Sensor and Codman® Microsensor devices are comprised of different patient contacting materials. Both devices have satisfied biocompatibility testing. The difference in materials do not raise new questions in terms of safety or effectiveness.
MRI Claim	MR Unsafe	1.5T and 3T Conditional	Braincare sensor is MR Unsafe. The difference in MR compatibility does not raise new questions in terms of safety and effectiveness.
Sterilization	Not applicable	Ethylene Oxide	Not applicable as the Braincare Sensor is a non-invasive device and is not provided sterile. The subject device contacts intact skin, and is to be disinfected between use with standard Ethanol 70%. Disinfection method of the Braincare device has been validated and does not raise new questions in terms of safety and effectiveness.
Shelf Life	Not applicable	2 years	
Device dimensions	Sensor case: 18,7 x 18,5 x 66,5 mm Sensor pin length: 18mm Sensor pin diameter: 7.5 mm Sensor cable length: 200 cm.	Microsensor: Length: 100cm nominal Tip diameter: 1.3mm max Tubing diameter: 0.8mm max	The Braincare Sensor and Codman® Microsensor have different dimensions due to the nature of the patient application and method of ICP measurement. The

	Headband Perimeter: Extra Small: 50-55cm, Small: 52.5-57.5 cm, Medium: 55-60 cm, Large: 57.5-62.5 cm. Adaptor cable length: 180 cm.	Catheter length (ventricular kit): 38cm nominal Catheter diameter (ventricular kit): 3.5mm max	differences in dimension do not raise new questions of safety or effectiveness.
Biocompatibility	Prolonged contact (>24 days but within ≤30 days) Non-cytotoxic Non-sensitizing Non-irritating	Prolonged contact (>24 days but within ≤30 days) Non-cytotoxic Non-sensitizing Non-irritating	Both the Braincare Sensor and Codman® Microsensor are categorized as prolonged contact (>24 days but within ≤30 days). Both devices were demonstrated to be non-cytotoxic, non-sensitizing, and non-irritating.
Energy modality	5 volts DC when connected to ICP monitoring device	5 volts DC when connected to ICP monitoring device	Both the Braincare Sensor and Codman® Microsensor share the same energy modality.
Pressure output display parameters	Waveform	Millimeters of Mercury (mmHg) Waveform	The Braincare Sensor does not provide direct pressure measurement, as opposed to the Codman® Microsensor. However, both devices use strain gauge sensors and generate waveform outputs in response to mechanical waves generated by blood flow in the brain. Animal and clinical study data have shown similarities in the outputs of both devices in real-time ICP monitoring. The difference in pressure output display parameters does not raise new questions in terms of safety and effectiveness.
Sensing element	Strain gauge	Strain gauge silicon microchip	Both devices utilize a strain gauge in the sensing element.
Functional pressure range	Not applicable, does not measure absolute values of pressure.	-50 mmHg to 250 mmHg	The Braincare Sensor does not have a limit in functional pressure range. Comparable performance to the predicate device has

			been demonstrated in animal and clinical studies. This difference does not raise new questions in terms of safety and effectiveness.
Functional over pressure range without damage	Not applicable, does not provide absolute values of pressure, and does not have a specified functional pressure range.	-700 mmHg to 1250 mmHg	The Braincare Sensor does not have a limit in functional pressure range. Comparable performance to the predicate device has been demonstrated in animal and clinical studies. This difference does not raise new questions in terms of safety and effectiveness.
Input/ Output Impedance	350 ohms nominal	1000 ohms nominal	The Braincare Sensor and Codman® Microsensor differ in input/output impedance based on the differences in the devices' operating principles in monitoring ICP and their technical build. Both devices are designed to meet acceptable safety and effectiveness parameters, and present similar ICP morphology (waveforms) information on the connected patient monitor. Comparable performance to the predicate device has been demonstrated in animal and clinical studies. This difference does not raise new questions in terms of safety or effectiveness.
Output signal (sensitivity)	10 mV	7.5 mV absolute voltage span (Calculated based on Microsensor device's functional pressure range of -50 to 250 mmHg, 5V when connected to ICP monitor, and output signal	The two devices differ in sensitivity due to differences in their principle of operation of monitoring changes in ICP. Both devices are compatible for use with commercially available patient monitoring devices. Comparable performance to the predicate device has

		sensitivity 5 uV/V/mmHg)	been demonstrated in animal and clinical studies. This difference does not raise new questions in terms of safety or effectiveness.
Zero Drift	The Adapter cable can be used to adjust offset ±20 mV.	No greater than 5 mmHg over 30 days	The Braincare Sensor generates output in mV and the signal is interpreted by the user in the form of waveform morphology, while the Codman® Microsensor directly measures and provides absolute ICP values in mmHg. Offset functionality for both devices have been defined based on their respective principle of operation. Comparable performance to the predicate device has been demonstrated in animal and clinical studies. This difference does not raise new questions in terms of safety and effectiveness.
Electrical Safety	Complies with IEC 60601-1	Not Known	Predicate device 510(k) summary does not provide electrical safety information for comparison.
Electromagnetic Compatibility	Complies with IEC 60601-1-2	Not Known	Predicate device 510(k) summary does not provide EMC information for comparison.

Differences from Predicate:

The BcSs-PICNI-2000 Sensor has minor technological differences from the predicate. The subject device is applied over the scalp to non-invasively capture a signal that is processed to generate a waveform output for qualitative evaluation by the clinician. However, there are other neurological devices that include similar technological characteristics.

The following table provides a comparison of the technological characteristics between the BcSs-PICNI-

2000 Sensor and Reference Device BrainPulse (DEN140040).

Table 2 Technological Comparison to Reference Device

	Braincare BcSs-PICNI-2000 Sensor	Reference Device: BrainPulse (DEN140040)	Remarks
Clinical Application	Non-invasive application to scalp	Non-invasive application to scalp	Same as Reference Device
Sensor operating principle	Strain gauge sensor detects skull deformation resulting from ICP changes	Accelerometer detects skull motion	Similar to Reference Device
Device output	Signal is processed to display waveform for qualitative assessment	Signal is processed to display waveform for qualitative assessment	Similar to Reference Device

Discussion of Performance Data

The following performance data in **Table 3** are provided in support of the substantial equivalence determination between the proposed device, BcSs-PICNI-2000 Sensor, and predicate device, Codman® Microsensor Basic Kit (K153347).

Table 3 Summary of Non-Clinical Performance Data

TEST	TITLE/TEST METHOD SUMMARY	RESULTS
Biocompatibility		
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass Non-cytotoxic
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass Non-sensitizing Non-irritating
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
Disinfection		
Disinfection Validation	Validation of Low-Level disinfection method using 70% ethanol.	Pass 6-log microbial reduction
Bench Testing		
Monitor Compatibility	Demonstration of compatibility for use with patient monitors.	Pass
Stability and Reproducibility	Demonstration of stability of device output waveform for a patient throughout a single monitoring session, and reproducibility across multiple monitoring sessions including reapplication of device by different practitioners.	Determined estimated range of variability in waveform characteristics with respect to stability and reproducibility. Results indicate excellent stability and some variance in reproducibility.
Animal Studies		
Direct Comparison Study in Rat Animal Model	Simultaneous intracranial pressure monitoring with the proposed device and predicate device were applied to 7 rats that received saline injected into the spinal channel to produce dynamic ICP changes. The objective was to measure the linear correlation between the two ICP monitoring devices' outputs.	Pearson's correlation coefficient r = 0.8±0.2 indicates a positive correlation between the ICP monitoring outputs of the proposed and predicate devices.
Direct Comparison Study in Swine Animal Model	Simultaneous intracranial pressure monitoring with the proposed device and predicate device were applied to a swine animal model that underwent saline injected into the spinal channel to produce dynamic ICP changes. The objective was to measure the monotonic correlation between the two ICP monitoring devices' outputs.	Spearman's correlation coefficient r= 0.81 ± 0.24 indicates positive correlation between the ICP monitoring outputs of the proposed and predicate devices.

Performance test results demonstrate that the BcSs-PICNI-2000 Sensor and predicate device, Codman® Microsensor Basic Kit (K153347), are substantially equivalent with respect to biocompatibility, and

intended use in continuous intracranial pressure monitoring in two comparative animal studies. Additional non-clinical testing verified device performance characteristics that differed from the predicate.

Discussion of Clinical Testing

Braincare conducted two clinical studies during validation of the BcSs-PICNI-2000 Sensor. An overview of each study is provided below:

Non-Invasive ICP Monitoring for HIV-associated Cryptococcal Meningitis

Participants

A critically ill adult patient diagnosed with human immunodeficiency virus-associated cryptococcal meningitis underwent real-time ICP monitoring.

Dataset Description

Four non-invasive ICP monitoring sessions were conducted at defined time points before and after treatment to yield four ICP curves for assessment.

Study Objective

The goal of this early study was to evaluate the ability of the BcSs-PICNI-2000 Sensor to non-invasively monitor changes in ICP for a patient with suspected intracranial hypertension such that morphological changes are consistent with the patient's clinical status.

Study Procedures

The patient underwent standard treatment for cryptococcal meningitis over thirty-four (34) days. During this period, non-invasive ICP monitoring was performed on Day 12 and Day 34 prior to and following a programmed lumbar puncture procedure. Monitoring produced ICP waveforms at 4 timepoints. Waveform morphology of the ICP curves at these time points was visually assessed with other recorded clinical parameters to determine whether the waveforms were indicative of the clinical status of the patient.

Study Outcomes

The pulsatile waveform from ICP monitoring on Day 12 before lumbar puncture revealed P2>P1, amplitude of tidal wave greater than that of percussion wave, reflecting characteristics of relative peak height consistent with the presence of neurological symptoms. P1<P2 after lumbar puncture, demonstrating improvement towards the characteristic P1>P2>P3, where P3 is dicrotic wave, as expected with reduction in ICP post-treatment. Morphology of the waveforms obtained from Day 34 were more closely representing

normal brain compliance (P1>P2>P3), which is consistent with reduction in ICP following the series of treatment and discharge that same day.

Study Conclusions

Results of this study demonstrated that the BcSs-PICNI-2000 Sensor is able to continuously monitor ICP changes to acquire signals consistent with the patient's clinical status.

Analysis of a Non-Invasive ICP Monitoring Method in Patients with Traumatic Brain Injury

Participants

Seven adult patients who were admitted to the neurointensive care unit and presented with severe or moderate brain injury with secondary neurological deterioration requiring intubation and mechanical ventilation were enrolled in the study.

Dataset Description

Total number of subjects: 7 patients

Range of acquisition time: 68-282 hours

Total acquisition time: 608 hours

Total acquisition time analyzed: 337 hours

Collected data: Simultaneous and continuous recordings of invasive ICP (iICP), noninvasive intracranial pressure (nICP), arterial blood pressure (ABP).

Study Objective

The objective of the study was to verify the similarities between the iICP (predicate device) and nICP waveforms. This assessment sought to provide evidence for the use of the noninvasive sensor as an alternative to invasive ICP assessments in situations where the waveform can provide supplementary clinical information. In addition, the noninvasive intracranial pressure and arterial blood pressure (ABP) waveforms were compared to verify the possible influence of the extracranial peripheral circulation into the noninvasive intracranial pressure signal, acknowledged as a potential limitation of the Braincare BcSs-PICNI-2000 sensor.

Study Procedures

Each patient underwent continuous ICP monitoring using both the predicate and subject devices concurrently from point of admittance throughout their stay in the neurointensive care unit, with acquisition time ranging from 68-282 hours. ABP measurement directly through the radial artery and partial pressure

of carbon dioxide (PaCO2) were also recorded simultaneously during the monitoring sessions. Approximately 337 total hours of recordings were analyzed.

Study Outcomes

The primary endpoint was the comparison of ICP waveform morphology obtained with the nICP and iICP sensors. A secondary endpoint was the comparison of the nICP and ABP waveforms. Waveforms were compared in a lower dimensional space constructed based on signals in the frequency domain. Similarity between the two devices' signals was inferred from the Euclidean distance between the non-linear projection in a lower dimensional space of the window power spectral densities (PSD) of the respective signals, in which PSD was calculated using the short-term Fourier transform. Intraindividual statistical comparisons were performed using the non-parametric Mann-Whitney U test for not normally distributed data points with a significance level set at $p<0.05$. Measurement of similarities are presented in the following table.

Table 4 - Measure of similarities between i-ICP, nICP and ABP

Patient ID							
Similarities	1	2	3	4	5	6	7
iICP-niICP	35.0	27.2	26.9	16.9	36.3	54.7	30.3
ABP-nICP	117.3	86.6	86.9	77.9	78.1	106.6	76.3

The difference between the iICP-nICP and nICP-ABP was found to be statistically significant for all seven patients, $p<0.05$, using the Mann-Whitney U test.

Study Conclusions

The study results demonstrate that a greater similarity exists between the waveforms generated from the signals of the subject and predicate device, than between the subject device and ABP measurements. Although the study had a limited sample size, the intra-individual similarities of the invasive and noninvasive ICP signals as functions of time suggest comparable effectiveness of ICP monitoring between the Braincare Sensor and the invasive Codman Microsensor ICP (K153347), which is representative of the standard of care. Additionally, no adverse events related to use of the Braincare sensor were reported,

supporting that the noninvasive device does not raise new questions of safety.

Benefit Risk Assessment

The main technological differences between the BcSs-PICNI-2000 Sensor and predicate device, Codman® Microsensor Basic Kit (K153347), are that the subject device noninvasively monitors ICP variation without measuring absolute ICP and outputs only the ICP waveform for qualitative review by the clinician. As such, the subject device presents reduced benefit by not offering the ICP value in addition to the waveform, but offers the clinician a method to initially assess patients with suspected variation in ICP or brain compliance to then determine the additional clinical assessments and parameters necessary to make an informed decision. Clinicians continue to use compatible patient monitors to view the ICP waveform and interpret and utilize the waveform in the same manner whether it is captured with the subject or predicate devices.

The subject device design and noninvasive application present reduced risk compared to the predicate by eliminating some known serious risks associated with invasive ICP monitoring devices such as infection, vascular complications, tissue lesions, device occlusion, and device migration. Accordingly, the device may be suitable for use to monitor some patients for whom benefits of monitoring with the predicate device, or similar invasive ICP monitoring devices, do not outweigh the potential risks.

The magnitude of benefits offered by the subject device is high. Foreseeable potential risks are of low severity with high detectability, temporary duration in nature, and low uncertainty. Non-clinical testing data showed that the device satisfied all performance criteria to support its intended use and context including electrical safety, electromagnetic compatibility, monitor compatibility, stability and reproducibility of the device output, and effective mitigation of risks to acceptable levels. Animal and clinical studies directly compared performance of the subject device to the predicate, demonstrating that both devices effectively provide continuous waveform morphology consistent with the patient's clinical state, and revealed no occurrence of adverse events when using the subject device. As is true with utilization of the predicate device's output, the clinician is expected to have appropriate knowledge to assess the suitability of the output and to review the waveform together with other clinical parameters to make decisions. The sponsor thus concluded that the benefits of the subject device outweigh the potential risks and that the device is at least as safe and effective as the predicate device when used to monitor variation in ICP by providing waveforms for clinician interpretation.

Conclusion

In summary, the BcSs-PICNI-2000 Sensor and predicate device, Codman® Microsensor Basic Kit

(K153347), are substantially equivalent with respect to intended use, biocompatibility, and performance. Non-clinical and clinical testing results support that the subject device and predicate device are equivalent in function for use in continuous intracranial pressure monitoring to produce waveform morphology reflective of alteration in ICP and changes in brain compliance. The differences between the two devices do not raise new questions regarding safety and effectiveness.