March 13, 2025

Bioserenity Medical Devices Group
Melanie Renaud-Samiri
Head of Regulatory and Quality Affairs
20, rue Berbier du Mets
Paris Cedex 13 lle-de-France
Paris, 75013
France

Re: K243788
Trade/Device Name: IceCap product line
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 14, 2025
Received: February 14, 2025

Dear Melanie Renaud-Samiri:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Physical Medicine 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)*

K243788

Device Name

IceCap product line (IceCap 2, IceCap 2 Small, IceCap Neonate (Sizes XS, S, & M))

Indications for Use *(Describe)*

The IceCaps are medical devices used as EEG electrodes. They are used by Healthcare Professionals on a patient in case of neurological disorders with a short or long-term EEG record (up to 72 hours).

IceCap 2 shall be placed on patients weighing at least 10 kg (22.05 lbs) and having a head circumference above 43 cm (16.93 inches).

IceCap Neonate shall be placed on the head of babies, newborns and premature babies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K243788

510(k) Summary

Prepared on: 2025-03-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BIOSERENITY MEDICAL DEVICES GROUP
Applicant Address	20, rue Berbier du Mets PARIS CEDEX 13 Ile-de-France, FR 75013 PARIS 75013 France
Applicant Contact Telephone	33-682581979
Applicant Contact	Mrs. Aude Gourgues
Applicant Contact Email	aude.gourgues@bioserenity.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IceCap product line
Common Name	Cutaneous electrode
Classification Name	Electrode, Cutaneous
Regulation Number	882.1320
Product Code(s)	GXY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151576	Neon EEG	GXY
K223644	Neuronaute with IceCap 2 & IceCap 2 Small	GWQ

Device Description Summary

21 CFR 807.92(a)(4)

The IceCaps (IceCap 2, IceCap 2 Small, IceCap Neonate (Sizes XS, S, & M)) are medical devices used as EEG electrodes.

The IceCaps are a single use cap which connects to the marketed EEG recorders using an IceAdapter or Touchproof adapter.

The electrodes placement in IceCap Product line is done accordingly to the 10/20 system.
The conductive tracks of the Flexible Printed Circuit are used to conduct EEG signals from the electrodes to the connectors.

IceCap 2 shall be placed on patients weighing at least 10 kg (22.05 lbs) and having a head circumference above 43 cm (16.93 inches).
IceCap Neonate (M,S,XS) shall be placed on the head of babies, newborns and premature babies.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The IceCaps (IceCap 2, IceCap 2 Small, IceCap Neonate (Sizes XS, S, & M)) are medical devices used as EEG electrodes. They are used by Healthcare Professionals on a patient in case of neurological disorders with a short or long-term EEG record (up to 72 hours).

IceCap 2 shall be placed on patients weighing at least 10 kg (22.05 lbs) and having a head circumference above 43 cm (16.93 inches).

IceCap Neonate shall be placed on the head of babies, newborns and premature babies.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The IceCap product line and two predicate devices share similar indication for use. They are intended to be used as EEG electrodes.

The only difference is the duration of use for predicate Neon EEG (K151576) is 12 hours whereas, 72 hours for IceCap product line. This duration is the same as already cleared predicate Neuronaute with Icecap 2 & Icecap 2 small (K223644).

Technological Comparison 21 CFR 807.92(a)(6)

The IceCap product line and two predicate devices share the similar intended use, principle of operation and same main technological characteristics. They just differ in number of electrodes in their electrode array. This difference is due to adaptability of the head circumference of the patients.

The minor differences between the IceCap product line and two predicate devices raise no new issues of safety or effectiveness. The performance data demonstrate that the IceCap Product line is safe and effective in use. Therefore, it is substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

IceCap product line was tested and conformed to following standards:
- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601- 1:2005/AMD2:2020
- IEC 60601-1-2: 2014 + A1 (2020)
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601- 1:2005/ AMD1:2012, IEC 60601-1:2005/AMD2:2020

The clinical data were not necessary to determine substantial equivalence. Hence, this section is not applicable.

As demonstrated in the Substantial Equivalence Comparison Table the IceCap product line maintains most of the features of the predicate device. IceCap product line does not pose new risks compared to its predicate devices. Any differences were minor and will not prevent a healthcare professional from being able to use the device to arrive at a clinical diagnosis, and there is no impact on safety and effectiveness.

Based on the similarities and differences concerning the indications for use, operation, and design, the conclusion established that IceCap product line is as safe, effective, and performs as well as both predicate device. The information presented in the premarket notification is complete and supports a substantial equivalence .

Substantial Equivalence Comparison Table:

Substantial Equivalence Topic	IceCap Product line	Neon EEG	Neuronaute with IceCap 2 & IceCap 2 small	Significant Differences
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
Device Classification Name	electrode, cutaneous	electrode, cutaneous	full-montage standard electroencephalograph	Predicate device (2) is approved as part of a full electroencephalograph system however, subject device and Predicate device (1) are only electrodes with their adapters.
Review Panel	Neurology	Neurology	Neurology	None
Regulation Number	882.1320	882.1320	882.1400	Predicate device (2) is approved as part of a full electroencephalograph system however, subject device and Predicate device (1) are only electrodes with their adapters.
Product Codes	GXY	GXY	GWQ /GXY	Predicate device (2) is approved as part of a full electroencephalograph system. Therefore additional classification code is used. however, subject device and Predicate device (1) are only electrodes with their adapters.
Device Class	II	II	II	None
Intended use/Indications For Use	The IceCaps are medical devices used as EEG electrodes. They are used by Healthcare Professionals on a patient in case of neurological disorders with a short or long-term EEG record (up to 72 hours). IceCap 2 shall be placed on patients weighing at least 10 kg	The NEON EEG is intended to be applied directly to the patient's scalp to enable recordings of electrophysiological signals (such as EEG) on infants from birth. The NEON EEG is indicated for single use only and should be replaced after 12 hours of use. The NEON EEG is not indicated for use with electro stimulation equipment	Neuronaute with IceCap 2 & IceCap 2 Small is a system intended to acquire, display, store, archive, and periodically transmit EEG signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. It allows remote access by users via the Neuronaute N-CLOUD which receives EEG signals	The indication for use is similar. They are intended to be used as EEG electrodes. The predicate device (1) is indicated for 12 hours of use only whereas, subject device can be used up to 72 hours of use, which is same as predicate device (2).

Substantial Equivalence Topic	IceCap Product line	Neon EEG	Neuronaute with IceCap 2 & IceCap 2 small	Significant Differences
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
	and having a head circumference above 43 cm. IceCap Neonate shall be placed on the head of babies, newborns and premature babies.		from Neuronaute Head Module which sends transmissions to the cloud. Neuronaute and its associated software are intended to assist in the diagnosis of neurological disorders. Neuronaute and its components do not provide any diagnostics conclusions or automated alerts of an adverse clinical event about a patient's clinical condition. The device is for use by trained medical professionals for patients under medical supervision. The device is intended for use on adults and pediatrics. Neuronaute is not intended to replace direct communication with healthcare providers. The system data should not be used alone but should be used along with all other clinical data and exams to come to a diagnosis.	The verification test for IceCap product line qualifies 72 hours of use. This duration of use does not raise any new concern for safety and effectiveness.
Prescription or OTC Use	Prescription	Prescription	Prescription	None
Intended User(s)	Trained Healthcare professionals	Trained Healthcare professionals	Trained Healthcare professionals	None
Environment of use	Physician's office, hospital or other remote locations under medical supervision.	Not indicated	Physician's office, hospital or other remote locations under medical supervision.	None
Type of components in contact with the patient	IceCap 2 & 2 small: Silicone adhesive Dielectric ink EEG conductive paste	- Ag/AgCl ink -adhesive (material unknown) - EEG conductive paste	IceCap 2 & 2 small: Silicone adhesive Dielectric ink EEG conductive paste	The material of adhesive used for Predicate (1) is unknown. However, the subject devices are biocompatible and compliant

Substantial Equivalence Topic	IceCap Product line	Neon EEG	Neuronaute with IceCap 2 & IceCap 2 small	Significant Differences
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
	Neonate: - Ag/AgCl ink - Polyolefin foam on acrylic adhesive			with standard ISO 10993-1 Fifth edition 2018-08 The difference does not affect the safety and the effectiveness. Therefore, IceCap product line is substantially equivalent to its predicate devices.
Storage life	12 months	20 months	12 months	The predicate device (1) indicates 20 months storage life whereas, subject device indicates 12 months of storage life, which is same as predicate device (2). The difference does not affect the safety and the effectiveness. Therefore, IceCap product line is substantially equivalent to its predicate devices.
Electrodes	IceCap 2 & 2 small: Up to 21 electrodes: • 19 EEG electrodes • 1 electrode (Fpz) used as reference for EEG calculation • 1 electrode (Oz) used for ground connection Neonate: • 11 EEG electrodes (size M) Or 9 EEG electrodes (size XS, S) • 1 ground connection • 1 reference for EEG calculation	6 EEG electrodes Or 10 EEG electrodes • 1 ground connection • 1 reference for EEG calculation	IceCap 2 & 2 small: Up to 21 electrodes: • 19 EEG electrodes • 1 electrode (Fpz) used as reference for EEG calculation • 1 electrode (Oz) used for ground connection	The subject devices and predicate device (1) and (2) have 1 ground and 1 reference connection. The number of electrodes is different to accommodate different head circumference of the patient. Number of electrodes does not impact quality of signal as the subject device is qualified via fit to form test, impedance test and general quality of signal. The subject device does not raise any

Substantial Equivalence Topic	IceCap Product line	Neon EEG	Neuronaute with IceCap 2 & IceCap 2 small	Significant Differences
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
				new risk that can affect the safety and the effectiveness. Therefore, IceCap product line is substantially equivalent to its predicate devices.
Material Composition	IceCap 2 & 2 small: - Polyethylene terephthalate (PET) - Silver and Silver/Silver chloride conductive inks - Insulation inks - Stiff PETG film - Skin adhesive - Graphical ink - Silicone adhesive Neonate: - Polyethylene terephthalate (PET) - Silver and Silver/Silver chloride conductive inks - Insulation inks - Stiff PETG film - Protective polyolefin foam on acrylic adhesive - Graphical ink	- Ag/AgCl ink -adhesive (material unknown) - EEG conductive paste - other materials unknown	IceCap 2 & 2 small: - Polyethylene terephthalate (PET) - Silver and Silver/Silver chloride conductive inks - Insulation inks - Stiff PETG film - Skin adhesive - Graphical ink - Silicone adhesive	The subject devices are biocompatible and compliant with standard ISO 10993-1 Fifth edition 2018-08. The difference does not affect the safety and the effectiveness. Therefore, IceCap product line is substantially equivalent to its predicate devices.
Electrodes; single or reusable?	Single use, non-sterile	Single use, non-sterile	Single use, non-sterile	None
Montage	10/20 System	10/20 System	10/20 System	None
Able to accommodate different patient head sizes	The material of the Neuronaute with IceCap 2 & IceCap 2 Small stretches to fit the patient's head. It's provided in two sizes depending on the head circumference of the patient: - Head circumferences between 43 and 53 cm: use the IceCap 2 Small - Head circumference between 53	Neon EEG comes in two sizes : Neon 8: indicated to be used on patients having head circumferences less than 32 cm Neon 12: indicated to be used on patients having head circumferences more than 32 cm	The material of the Neuronaute with IceCap 2 & IceCap 2 Small stretches to fit the patient's head. It's provided in two sizes depending on the head circumference of the patient: - Head circumferences between 43 and 53 cm: use the IceCap 2 Small - Head circumference between 53	The subject and predicate devices cover different range of patient head size. The subject device is qualified via fit to form test and usability test for installation. The subject device does not raise any new risk that can affect the safety and the

Substantial Equivalence Topic	IceCap Product line	Neon EEG	Neuronaute with IceCap 2 & IceCap 2 small	Significant Differences
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
	and 60 cm: use the IceCap 2 The IceCap 2 is used when the patient is between 2 sizes. IceCap Neonate is provided in three sizes and intended to be used on patients having head circumferences at least 23 cm until 51 cm.		and 60 cm: use the IceCap 2 The IceCap 2 is used when the patient is between 2 sizes.	effectiveness. Therefore, IceCap product line is substantially equivalent to its predicate devices.
Conductive Electrolyte gel	Conductive gel	Conductive gel	Conductive gel	None
Component dimensions	IceCap2 – Height: 11.50 inches (292 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches ^2 (74.7 mm^2) IceCap2 Small - Height: 9.69inches (246 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches^2 (74.7 mm^2) IceCap Neonate M - Height: 10.38inches (263,8 mm) - Width: 8.33 inches (211,5 mm) - Sensor diameter: 0.64 inches (16,3 mm) IceCap Neonate S - Height: 11.32inches (287,5 mm) - Width: 8.34 inches (211,9 mm) - Sensor diameter: 0.60 inches (15,3 mm)	Neon 8: 97mm x 208mm x 6mm Neon 12: 178mm x 240mm x 9mm	IceCap2 – Height: 11.50 inches (292 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches ^2 (74.7 mm^2) IceCap2 Small - Height: 9.69inches (246 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches^2 (74.7 mm^2)	The subject and predicate devices vary in dimension due to difference in number of electrodes. The number of electrodes is different to accommodate different head circumference of the patient. The subject device is qualified via fit to form test and does not raise any new risk that can affect the safety and the effectiveness. The subject device has more sizes available compared to predicate (1) to provide precise fitting for intended patient population. Therefore, IceCap product line is substantially equivalent to its predicate devices.

Substantial Equivalence Topic	**IceCap Product line**	**Neon EEG**	**Neuronaute with IceCap 2 & IceCap 2 small**	**Significant Differences**
Relationship	**Subject device**	**Predicate device (1)**	**Predicate device (2)**	**N/A**
510(k) #	**K243788**	**K151576**	**K223644**	**N/A**
Establishment Name	BioSerenity Medical Devices Group	INCEREB LTD	Bioserenity	N/A
Owner/Operator	10089585	10051067	10057285	N/A
	IceCap Neonate XS - Height: 10.28inches (261,1 mm) - Width: 8.34 inches (211,9 mm) - Sensor diameter: 0.060 inches (15,3 mm)			
Accessories to connect with recorders on market	Touchproof Adapter IceAdapter via DB25 cable	Universal Connectivity (1.5mm Touchproof and D-type connectors)	Touchproof Adapter IceAdapter via DB25 cable	None