K082996

BRAINSCOPE

510(k) Summary

AUG 10 2009

The following information is provided as required by 21 CFR § 807.87 for BrainScope's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: BRAINSCOPE COMPANY INC.

1717 Rhode Island Avenue
9th Floor
Washington, D.C. 20036

Proprietary Name: ZOOM-100DC

Common Name: Electroencephalograph

Regulatory Class: Class II 21 CFR §882.1400
Product Codes: OLT & OMC

Predicate Device(s): Nicolet Bravo Multi-Modality System (K991054), Cleveland Medical Crystal-EEG Model 10 (K970672), Brainz Instruments Ltd BRM3 Brain Monitor (K071449) and Infinite Biomedical Technologies, LLC Model I-2000 Monitor (K072382).

Device Description:

The ZOOM-100DC records, measures and displays Electroencephalographic (EEG) waveforms which are digitized and processed.

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Indications for Use:

The ZOOM-100DC is used to measure and record the electrical activity of a patient's brain. The ZOOM-100DC is intended to monitor the state of the brain by acquisition and display of electroencephalogram (EEG) signals and by the calculation of standard quantitative EEG (qEEG) parameters.

Device Comparison Table:

	ZOOM-100DC	Bravo Multi-Modality System K991054	Crystal-EEG Model 10 (K970672)	BRM3 Brain Monitor (K071449)	Model 1-2000 Monitor (K072382)
Indication for Use	The ZOOM-100DC is used to measure and record the electrical activity of a patient's brain. The ZOOM-100DC is intended to monitor the state of the brain by acquisition and display of electroencephalogram (EEG) signals and by the calculation of standard quantitative EEG (qEEG) parameters.	The Bravo Multi-Modality System is intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third party monitoring devices such as vital signs monitors. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.	The Crystal-EEG Model 10 is a mobile, intermediate range, wireless EEG system intended to be used for measuring and transmitting electroencephalogram (EEG) signals.	A device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head. • The BRM3 Brain Monitor is intended for use to monitor the state of the brain by acquisition of electroencephalog ram (EEG) signals, in clinical environments such as the intensive care unit, and for clinical research. • The BRM3 Brain Monitor is intended for use only with neonatal patients, defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 24 to 46 weeks. • The BRM3 Brain Monitor does not provide any diagnostic conclusion about the patient's condition.	The 1-2000 Monitor is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the head. The 1-2000 Monitor is indicated for use in monitoring the state of the brain by acquisition of electroencephalogram (EEG) signals, in research and clinical environments.
Modalities	EEG	EEG, Evoked Potential EMG, CSA	EEG	EEG	EEG
Environment of Use	Hospitals and Clinics	Hospitals and Clinics	Hospitals and Clinics	Hospitals and Clinics	Hospitals and Clinics
Power Source	Li Ion Battery	120 Volt 60Hz AC power	Unknown	Unknown	Unknown

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Device Components	ZOOM-100DC External Patient Interface Cable External Audio Cable CF (Compact Flash) Card Battery Charger	PC running Microsoft windows NT Amplifier Unit Patient Interface Cables Evoked Potential Unit Evoked Potential Patient interface Cable	Unknown	Sensor Set (EEG skin electrodes) or Sensor Adaptor Set (electrode adaptor) Data Acquisition Unit (EEG head stage) Data Cable Monitor Power Supply Unit and Roll-Pole.	tablet PC battery powered wireless headbox headbox charger power conditioner
Electrode Material	N/A Uses Standard off the Shelf EEG electrodes	N/A Uses Standard off the Shelf EEG electrodes	N/A Uses Standard off the Shelf EEG electrodes	N/A	
Screen Display Details	Displays: Raw EEG Waveform	Displays: Raw EEG Wavefom Raw averaged AEP Waveform	Unknown	Displays: Raw EEG Waveform aEEG parameter Signal Quality	Displays: Raw EEG waveforms EEG power spectrum 95% Spectral Edge Frequency
Hard copy of Displayed Data	Yes – through CF (Compact Flash) card	Yes	Unknown	Unknown	Yes
Channels	10/20 Array 8 single-ended channels corresponding to 8 electrodes placed anywhere on the head, including but not limited to, all locations defined by the International 10/20 System. (5 differential channels can be viewed concurrently).	10/20 Array Up to 16 differential channels	8 channels	3 channels	2 channels
Real Time EEG Display	Yes	Yes	Yes	Yes	Yes
Real Time EEG Bandwidth	0.5-4000 Hz available	0.5 – 500 Hz Available EEG 100 – 20kHz Available AEP	Unknown	Unknown	Unkown
Processed EEG Bandwidth	0.5 - ~~45~~ 50Hz Hz -Shad 8/4/09	0.5 – 500 Hz	Unknown	Unknown	Unkown
Automatic Artifacting	Yes	Unknown	Unknown	Unknown	Unkown

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Amplifier Common Mode Rejection Ratio (CMRR)	≥100 dB	≥ 110 dB	Unknown	Unknown	Unkown
Amplifier Input Impedance	≥10 Meg Ohms	> 100 Meg Ohms	Unknown	Unknown	Unkown
Electrode Impedance Test	Yes	Yes	Unknown	Unknown	Yes
EEG Derived Measures	Yes- Derived from FFT* 1. Absolute Power a. Monopolar Power b. Bipolar Power 2. Relative Power a. Relative Monopolar Power b. Relative Bipolar Power 3.Mean frequency variables (univariate and multivariate) a. Monopolar Mean Frequency b. Bipolar Mean Frequency 4. Coherence a. Monopolar Coherence b. Bipoloar Coherence 5. Asymmetry a. Monopolar Asymmetry b.Bipolar Asymmetry	Yes- Derived from FFT*	N/A	N/A	N/A

* See comparison of measures in section 12.3.

Conclusion

The ZOOM-100DC, when compared to its predicate devices, has the same intended use and equivalent technological characteristics. Performance data demonstrate that the device performs equivalently to the predicate devices. The ZOOM-100DC is substantially equivalent.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Brainscope Company Inc.
% Mr. Michael E. Singer
1717 Rhode Island Avenue, 9th Floor
Washington, District of Columbia 20036

AUG 10 2009

Re: K082886
Trade/Device Name: ZOOM-100DC
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, OMC
Dated: July 24, 2009
Received: July 28, 2009

Dear Mr. Singer:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter D Rumm MD MPH
D&P D.A.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082886

Device Name: ZOOM-100DC

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082886