K050192

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510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

The Anson Group
7992 Castleway Dr., Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Carri Graham

Date: October 14, 2005

Manufacturer: BRC Operations Pty.Ltd, P.O. Box 737 Broadway
Sydney, NSW 2007 Australia

807.92(a)(2)

Trade Name: BRC Software Product

Common Name: Electroencephalograph

Classification Name(s): Electroencephalograph

Classification Number: 882.1400

807.92(a)(3)

Predicate Device(s)

K974748	Neurometric Analysis System	Nxlink, Ltd
K010669	NeuroGraph	Thuris Corp.
K041263	NeuroGuide	Applied Neuroscience

K050192

807.92 (a)(4)

Device Description

The BRC software product is composed of the following major components: BRC Neuromarker Data Acquisition Software and the BRC Neuromarker Analysis Software. The Neuromarker Data Acquisition Software is used to collect the data gathered at BRC licensed laboratories. Identical acquisition protocols and equipment are utilized at each BRC laboratory to ensure uniformity of collected data. The data is then transmitted to the BRC Central Analysis Facility where the Neuromarker Analysis Software is used to process the gathered data against the Brain Resource International Database (BRID). The database currently contains data from approximately 2,400 normative (i.e., without a history of mental illness, drug/alcohol abuse, or serious medical condition) participants. The results of the processed data is compiled into an individualized report called the NeuroMarker Report.

The BRC Cognition Acquisition Software is one component of the BRC NeuroMarker Acquisition Software and which is loaded on a computerized touchscreen system and used to gather cognitive patient performance information. This data is transmitted from the BRC laboratory to the BRC Central Analysis Facility for processing and formatting into report form (IntegNeuro Report).

The BRC software product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP).

807.92(a)(5)

Intended Use(s)

The BRC software product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP).

807.92(a)(6)

Technological Characteristics

	BRC Software Product To be cleared via this submission	Applied Neuroscience NeuroGuide K041263 Exhibit A	Thuris Corp. NeuroGraph K010669 Exhibit B	NxLink Neurometric Analysis System (NAS) K974748 Exhibit C
EEG data comparison against normative database	Yes	Yes	Yes	Yes
ERP/EP data comparison against normative database	Yes	No	Yes	Yes
Population	6 to 90 years	Birth to 82 years	Unknown	6 to 90 years
Product code	GWQ-EEG	GWQ-EEG	GWQ-EEG	GWQ-EEG
Classification	882.1400	882.1400	882.1400	882.1400
Indications for Use	See attached	See Exhibit B	See Exhibit A	See Exhibit C
Web Questionnaire	Yes	No	No	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

BRC Party Limited
c/o Carri Graham
The Anson Group, LLC
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K050192
Trade/Device Name: BRC Software Product
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: October 14, 2005
Received: October 18, 2005

Dear Ms. Graham:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050192

Indications for Use

510(k) Number (if known): K050192

Device Name: BRC Software Product

Indications For Use:

The BRC software product is to be used by qualified medical professionals for the post-hoc statistical evaluation of the human electroencephalogram (EEG), utilizing evoked response potentials (ERP).

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 General, Restorative, and Neurological Devices

510(k) Number K050192