K070085

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FEB 26 2007

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

Medicaa (Uruguay) S.A.
Miraflores 1476
11500, Montevideo
Uruguay
Phone: +(598) 2 601 3998
Fax: +(598) 2 601 3839

Contact Person: Rodolfo Oppenhemier, CEO
roppenheimer@medicaa.com

Date Prepared: December 21, 2006

II. Device Name

Proprietary Name:	BRU™ – Balance Rehabilitation Unit
Common/ Usual Name:	Apparatus, vestibular analysis Platform, force-measuring
Classification Name:	Unclassified / Force-measuring platform
Regulation Number:	Unclassified / 890.1575
Product Codes:	LXV / KHX
Classification:	Unclassified / 1
Classification Panel:	Ear, Nose& Throat / Physical Medicine

III. Predicate Device

The Balance Rehabilitation Unit (BRU™) is substantially equivalent to the Balance Manager from Neurocom International, Inc. The Balance Manager was cleared by the FDA on August 4, 1995 under 510(k) K946229.

IV. Intended Use of the Device

Balance Evaluation and Rehabilitation

The Balance Rehabilitation Unit (BRU™) is a system that enables the functional assessment and training/retraining of patients with balance disorders, vertigo or instability.

V. Description of the Device

The Balance Rehabilitation Unit (BRU™) is composed of a static force platform, virtual reality projection goggles, a head tracker for sensing head movements, a safety frame, a harness, an accessory kit for different exercises, and a computer to generate stimuli.

The system performs a sequence of posturographies while the patient is receiving different visual stimuli (images displayed on the projection goggles). By using the different stimuli to identify the patient's weakness a tailored rehabilitation program with specific perceptual cues can be designed for each patient.

VI. Summary of the Technical Characteristics

The Balance Rehabilitation Unit (BRU™) performs an assessment of the impaired postural skills of patients through a series of posturographies with different sensory stimuli. The posturographies are performed using a force-measuring platform, which helps the physician evaluate the patient's performance. The sensory stimuli used with the Balance Rehabilitation Unit (BRU™) include visual stimuli, through virtual reality projection goggles, somatosensorial stimuli, and vestibular stimuli.

VII. Testing

A clinical study has confirmed the clinical efficacy of the Balance Rehabilitation Unit (BRU™).

VIII. Safety & Effectiveness

There are no substantial differences between the Balance Rehabilitation Unit (BRU™) and the predicate device. They have the same intended use and similar technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medicaa (Uruguay) S.A.
C/O Ian P. Gordon
Vice President
Emergo Group, Inc.
1101 South Capital Texas Hwy, Suite F254
Austin, TX 78746

FEB 26 2007

Re: K070085
Trade/Device Name: Balance Rehabilitation Unit (BRU™)
Regulation Number: Unclassified
Regulation Name: Vestibular analysis apparatus
Regulatory Class: Unclassified
Product Code: LXV and KHX
Dated: December 26, 2006
Received: January 10, 2007

Dear Mr. Gordon:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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4. Indication for Use Statement

510(k) Number (if known):

Device Name: Balance Rehabilitation Unit (BRU™)

Indications for Use:

Balance Evaluation and Rehabilitation

The Balance Rehabilitation Unit (BRU™) is a system that enables the functional assessment and training/retraining of patients with balance disorders, vertigo or instability.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K070085