DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 - 2005

Mr. John Radke
Bio-Research Associates, Inc.
9275 North 49th Street
Brown Deer, Wisconsin 53223

Re: K981563
Trade/Device Name: Biopak Measurement System
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: II
Product Code: KZM and NFS and NFQ
Dated: August 12, 1998
Received: August 14, 1998

Dear Mr. Radke

This letter corrects our substantially equivalent letter of September 15, 1998, regarding the classification of your device which was incorrectly identified as "unclassified."

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 (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 Rerister.

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 continue 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" (21 CFR 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,

Jennifer S. Michaud MD

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K981563
Device Name: BioPak Measurement System [ ] = ADD
Indications for Use:

At the present time, comparisons between patients of electromyograms, sonograms and / or jaw traces should not be made.

Sufficient normative data have not been collected to support such population-based measurements as "mean electromyographic clench," "standard deviation (Jaw Tracking) of freeway space," "integral (sonograph) of sound intensity," "average jaw tracing of chewing," etc., for non diseased individuals as well as for patients having various disease entities that are now lumped within the terminology known as "Temporomandibular Disorders and Associated Orofacial Pain (TMD/MPD)."

Jaw Tracking

[ ] = OUT

1. To track mandibular movement and position
2. To aid in the diagnosis of TMJ / MPD syndrome, muscle tension and bruxing [instability of occlusion]
3. To identify mandibular rest position and to identify interocclusal distance and freeway space
4. To monitor the position of the jaw in three dimensions
5. To represent the spatial position of the mandibular incisal edge relative to the skull
6. To provide Baseline measurements for future reference

Electromyography

1. To record electrical activity of muscles of the stomatognathic system, especially temporalis, masseter and digastric
2. To clinically monitor up to eight different muscles as an aid in diagnosis and treatment evaluation by recording the electrical activity of the muscles of the stomatognathic system.
3. To determine the degree of relaxation (intra-patient) of a single muscle / group of muscles at rest
4. To measure relative (intra-patient) levels of activity of several muscles during a functional act
5. To provide Baseline measurements for future reference

Sonography, joint vibration (sound) recording

1. To record and display sounds / vibrations from the temporomandibular joint
2. To aid the clinician in his analysis of a joint sound / vibration by allowing him to see the waveform in various standard plots
3. To aid the clinician in comparing a patient's current standard plots to previous recordings before, during and after treatment
4. To provide numerical values that can be used to quantify the physical characteristics of the sounds / vibrations, allowing intra-patient comparisons (only) by the clinician
5. To provide Baseline measurements for future reference

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981563

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)