



MAY 23 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**RECEIVED**

**MAY 27 2005**

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

Re: K003176  
Trade/Device Name: BioEMG II and BioJVA  
Regulation Number: 21 CFR 890.1375  
Regulation Name: Diagnostic electromyograph  
Regulatory Class: II  
Product Code: KZM and NFQ  
Dated: October 6, 2000  
Received: October 11, 2000

Dear Mr. Radke

This letter corrects our substantially equivalent letter of January 4, 2001, 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 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 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,



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:  
Device Name: BioEMG II / BioJVA  
Indications for Use:

K 003176

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)."

**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

**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

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR  
Susan Puma  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K003176

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)