MAY 19 [illegible] K990538 **EXHIBIT #1**

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

BrainMaster
6588 Woodhawk Drive
Cleveland, Ohio 44124

Date Summary Prepared: Contact: Thomas F. Collura, Ph.D.
October 1998

2. Name of the Device:

The BrainMaster™ 2E

3. Predicate Device Information:

1. The Lexicor NRS-2D, Lexicor Medical Technology, Inc., Boulder, Colorado, K#961645.

2. Stoelting AT 62 EEG, Stoelting Company, K#965006.

4. Device Description:

Executive Summary and Device Description:

This two-channel digital Biofeedback/EEG device uses industry-accepted standard Windows - based PC as control and display console. The device consists of the following:

a) BrainMaster™ 2E Hardware Module
b) BrainMaster™ BMT (basic educational/research SW)
c) BrainMaster™ PT (clinical SW)

The System uses commercially available standard EEG electrodes and pastes such as 9 mm gold disks with 10 - 20 paste.

5. Intended Use:

The BrainMaster™ 2E is indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, BrainMaster™ provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation.

6. Comparison to Predicate Devices:

a. Table of Comparison to Legally Marketed Devices:

The following is a Comparison Chart outlining differences and similarities between the BrainMaster™ 2E device and the Lexicor NRS-2D/Stoelting AT 62 EEG devices:

Device Parameters	BrainMaster™ Type 2E Device	NRS-2D Device	Stoelting Autogenice AT62
Software	BMT	BioLex	AT62
Interface	Serial Port	Parallel Port	none – standalone
Channels	1 or 2	1 or 2	one
Sampling Rate	120 / second	128 / second	N/A
Notch Filtering	40 Hz cutoff	50 or 60 Hz	none
Common Mode Rejection	>100 dB	>90 dB	120dB
Gain	20,000	8000	50,000
Sampling	8 bit	12 bit	N/A
Input Impedance	10 M ohms	>1 G ohm	200 K ohms
Operating System	Windows	MS-DOS	built-in
Frequency Analysis	Digital Filtering	FFT	Analog Filtering
Power	rechargeable batteries	medical grade power supply	rechargeable batteries

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Section 7 - Electrical, Mechanical and Environmental Testing

Testing information demonstrating safety and effectiveness of The BrainMaster™ Type 2E in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

Testing was conducted by a contract testing laboratory on the BrainMaster™ 2E device per IEC 60601-1 (electrical isolation).

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards.

It was a contract testing laboratory conclusion that BrainMaster™ 2E tested product met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by a contract testing laboratory:

Radiated and Conducted Electromagnetic Energy and Magnetic Field Testing on the BrainMaster™ 2E. Testing was conducted per the DCRND Reviewer's Guideline, November 1993. All testing met required parameters.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The BrainMaster™ 2E device is substantially equivalent in intended use, design, material and technology as the Lexicor NRS-2D/Stoelting AT 62 EEG devices. All devices use EEG Signals, measure EEG and process it to produce frequency band energy. Differences do not affect functionality of the device thus, when compared to the predicate device, The BrainMaster™ 2E does not incorporate any changes in intended use, method of operation, material or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1999

BrainMaster
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K990538
Trade Name: The BrainMaster 2E
Regulatory Class: II
Product Code: HCC and GWQ
Dated: February 17, 1999
Received: February 19, 1999

Dear Ms. Goldstein-Falk:

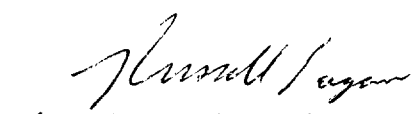
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

510(k) NUMBER (IF KNOWN): K990538

DEVICE NAME: **The BrainMaster™ 2E**

INDICATIONS FOR USE:

The BrainMaster™ 2E is indicated for relaxation training using alpha EEG Biofeedback. In the protocol for relaxation, BrainMaster™ provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Kogan

for (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990538

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)