JAN 20 2000

K993824

THE HUMAN CALIBRATION COMPANY
BIOMERIDIAN

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

APPLICANT'S NAME/ADDRESS	BioMeridian, Inc. Draper, Utah 84020 12411South 265 West Suite F
Contact Person	Joe Galloway
COMMON/USUAL NAME:	Galvanic Skin Response Device
CLASSIFICATION NAME:	Galvanic Skin Response Device
ESTABLISHMENT REGISTRATION NUMBER:	**1723429**
CLASSIFICATION:	The Galvanic Skin Response Measurement Device is classified into class II as described in Title 21, code of Federal Regulation 82.1540.
PERFORMANCE STANDARD:	BioMeridian Inc. is not aware of any special controls or performance standards established for this device under sections 513 or 514, respectively, of the Food, Drug and Cosmetics Act.
SUBSTANTIAL EQUIVALENCE:	BioMeridian, Inc. believes the MAS-21 is substantially equivalent to the J&J G-25a GSR, and Global Corp.'s C-29

CORPORATE OFFICES
• TOLL-FREE PHONE (888) 224-2337
• TELEPHONE (801) 495-1188
• CORPORATE FAX (801) 495-1199
• SALES FAX (801) 495-2266

TRAINING AND EDUCATION
• TOLL-FREE PHONE (888) 765-4665
• TELEPHONE (801) 501-7517
• FAX (801) 501-7518

CUSTOMER SUPPORT
• TOLL-FREE PHONE (877) 404-2378
• TELEPHONE (801) 501-7517
• FAX (801) 501-7518

WWW.BIOMERIDIAN.COM
• GENERAL INFORMATION mail@biomeridian.com
• TRAINING AND EDUCATION training@biomeridian.com
• CUSTOMER SUPPORT helpdesk@biomeridian.com

BIOMERIDIAN INTERNATIONAL, INC
is a wholly owned subsidiary of Magellan Technology, Inc. (OTC: MGLN)
• MAGELLAN PHONE (801) 495-2211
• MAGELLAN FAX (801) 495-1199
• MAGELLAN SHAREHOLDER RELATIONS magellan-info@biomeridian.com

BioMeridian International, Inc. 13526 South 110 West Draper, Utah 84020 USA

The MSA-21 has undergone an extensive battery of tests to insure safety. The unit design was safety intense from the outset. Small details such as using a 3 pin mini Din connector for the electrode and a 7 pin mini Din connector for the probe so they could not be inserted into the wrong plug are just one example. This quest for safety included all MSA-21 accessories. BioMeridian, Inc. also submitted the MSA-21 to Intertek Testing Services for test and evaluation. The MSA-21 fully passed the following test:

Medical Electrical Equipment (see attachment # 3)

a) UL 2601-1
b) CSA C22.2 No 601.1

Medical Electrical Equipment, Part 1: General Requirements for Safety (see attachment # 4)

a) EN60601-1
b) IEC 601-1

Emissions and Immunity Testing (see attachment # 5)

a) EN60601-1-2:1993

In summary the MSA-21 meets or exceeds all the safety requirements for a medical device in its class. Our dedication to safety is evidenced in the many extra steps we have taken to insure a safe product. Also the MSA-21 has met all the requirements and has received a registered CE mark.

CORPORATE OFFICES
• TOLL-FREE PHONE (888) 224-2337
• TELEPHONE (801) 495-1188
• CORPORATE FAX (801) 495-1199
• SALES FAX (801) 495-2266

TRAINING AND EDUCATION
• TOLL-FREE PHONE (888) 765-4665
• TELEPHONE (801) 501-7517
• FAX (801) 501-7518

CUSTOMER SUPPORT
• TOLL-FREE PHONE (877) 404-2378
• TELEPHONE (801) 501-7517
• FAX (801) 501-7518

WWW.BIOMERIDIAN.COM
• GENERAL INFORMATION mail@biomeridian.com
• TRAINING AND EDUCATION training@biomeridian.com
• CUSTOMER SUPPORT helpdesk@biomeridian.com

BIOMERIDIAN INTERNATIONAL, INC
is a wholly owned subsidiary of Magellan Technology, Inc. (OTC: MGLN)
• MAGELLAN PHONE (801) 495-2211
• MAGELLAN FAX (801) 495-1199
• MAGELLAN SHAREHOLDER RELATIONS magellan-info@biomeridian.com

BioMeridian International, Inc. 13526 South 110 West Draper, Utah 84020 USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Mr. Joe Galloway
Vice President of Compliance
Biomeridian, Inc.
12411 South 265 West
Suite F
Draper, Utah 84020

Re: K993824
Trade Name: MSA-21
Regulatory Class: II
Product Code: GZO
Dated: December 21, 1999
Received: December 21, 1999

Dear Mr. Galloway:

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 James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number. K 993824

Device Name. MSA-21 (Meridian Stress Assessment)

Indications for Use. The MSA-21 intended use is for the measurement of Galvanic Skin Respons

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDE

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 993824

Prescription Use ✓ OR Over- The Counter Use _____

(Per 21 CFR 801.109)