MERIDIAN CO., LTD.

9Fl., Seoil Bldg., 222, Jamsilbon-Dong, Songpa-Gu, SEOUL, KOREA

Tel : 82.2.2103.3300 Fax : 82.2.2103.3333

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

APPLICANT'S NAME/ADDRESS :	MERIDIAN CO., LTD. 9Fl., Seoil Bldg., 222, Jamsilbon-Dong, Songpa-Gu, Seoul, Korea
CONTACT PERSON :	Soo-Rang Lee
COMMON/USUAL NAME :	Galvanic Skin Response Measurement
CLASSIFICATION NAME :	Galvanic Skin Response Measurement
OWNER/OPERATOR NUMBER :	9038705
CLASSIFICATION :	The Galvanic Skin Response Measurement Device is classified into Class II under 21 code of Federal Regulation 82. 1540
PERFORMANCE STANDARD :	MERIDIAN CO., LTD. is not aware of any Special Controls or Performance Standards established for Galvanic Skin Response Measurement Device under Section 513 and 514, respectively, of the Food and Drug and

Cosmetics Act.

SUBSTANTIAL EQUIVALENCE :	MERIDIAN CO., LTD. believes the ABR-2000 is substantially equivalent to the MERIDIAN-II and MERIDIAN-Plus.

Electrical safety of the ABR-2000 are achieved by means of reinforced or double insulated parts. Electrical isolation of at least 4000Vac between Applied Part(patient circuit) and Live Part. An isolation transformer isolates the primary line current from the secondary electronics of the system when the AC power cord is connected to the system. The connectors of the electrodes are uniquely designed to prevent accidental connection to an AC power outlet.

The ABR-2000 system underdone various electrical safety tests and certify the conformance to the following standards (See Attachment 3) :

1. EN 60601-1(IEC 601-1), Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.

2. EN 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

In summary the ABR-2000 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

Meridian Company, LTD.
Soo-Rang Lee
9Fl., Seoil Building
222 Jamsilbon-Dong
Songpa-Gu
Seoul, Korea

Re: K020360
Trade/Device Name: ABR-2000
Regulation Number: 882.1540
Regulation Name: Galvanic Skin Response Measurement
Regulatory Class: Class II
Product Code: GZO
Dated: May 30, 2002
Received: June 3, 2002

Dear Mr. Lee:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for

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

Enclosure

Indications for Use Statement

PMN 510(k) Number : K020360

Device Name : ABR-2000
(Galvanic Skin Response Measurement Device)

Indication for Use :

The ABR-2000 intended use is for the measurement of galvanic skin response.

Prescription use ✓

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020360