JUN 2 4 2003

K023355 1/1

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

APPLICANT'S NAME/ADDRESS	Galloway Technologies 3736 Panarama Drive Saratoga Springs, UT 84043-3247
CONTACT PERSON	Joe Galloway
COMMON/USUAL NAME	Galvanic Skin Response Device
CLASSIFICATION NAME	Galvanic Skin Response Device
ESTABLISHMENT REGISTRATION NUMBER	**Applied for** (Owner/Operator # 9051656)
CLASSIFICATION	The Galvanic Skin Response Measurement Device is classified into class II as described in Title 21, Code of Federal Regulations 82.1540
PERFORMANCE STANDARD	Galloway Technologies is not aware of any special controls or performance standards established this device under section 513 or 514, respectively, of the Food, Drug and Cosmetics Act
SUBSTANTIAL EQUIVALENCE	Galloway Technologies believes the Asyra is substantially equivalent to The J & J G-25a GSR device

The Asyra has Nemours safety features imbedded in the firmware to both monitor and test it's circuitry before and after each test. We have included double fault protection for the safety of the user and all information going into the system or out of the system is handled by an isolated infrared interface. The battery charger mechanically disconnects the measurement circuit when plugged in, thus isolating the Stylus Probe and Hand-Mass. Plugs for the Stylus Probe and Hand-Mass are wired such that if plugged in incorrectly no reading can be taken.

In summary the Asyra meets or exceeds all the safety requirements for a medical device in its class.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2003

Mr. Joe Galloway
Vice President of Compliance
Galloway Technologies LLC
3736 Panarama Drive
Saratoga Springs, Utah 84043

Re: K023355
Trade/Device Name: ASRYA
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic skin response measurement device
Regulatory Class: II
Product Code: GZO
Dated: April 23, 2003
Received: May 13, 2003

Dear Mr. Galloway:

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), 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" (21CFR Part 807.97) you may obtain. 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,

Miriam C. Provost

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

510(k) Number (if known): K023355

Device Name: Asyra

Indications For Use:

The Asyra's intended use is for the measurement of Galvanic Skin Response

Miriam C. Provost

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

510(k) Number K023355

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Forma