K033988
p 1 13

FEB 2 5 2004

510(k) Summary

1. Submitter's Identification:

Lee & Xiao
2600 Mission Street, Suite 100
San Marino, CA 91108
Tel: (626)799-0998
Fax: (626)755-1588

Contact Person: Yingchao Xiao, Esq.

Date: December 5, 2003

2. Device Name:

Trade Name: Goldway UT4000A Vital Signs Monitor
Common Name: Patient Monitor
Classification Name: Monitor, Physiological, Patient

3. Predicate Device Information:
The legally marketed device to which the submitter claims equivalence:

Goldway Model UT4000F Patient Monitor (K021154)

4. Device Description:

The Goldway UT4000A monitor interprets and displays physiological data of the patient including waveforms and numerical data in real time. Goldway UT4000A can be custom configured to monitor electrocardiograph (ECG), non-invasive blood pressure (NIBP), or pulse oximetry (SpO2). For each patient vital parameter, Goldway UT4000A will be capable of providing limit alarms and alerts, storing data trends for retrospective review and sending serial port signal to printer for report printing.

5. Intended Use:

Goldway UT4000A Vital Signs Monitor is intended to monitor basic physiological parameters of patients from adults to neonates within any professional medical environment. The user, responsible to interpret the monitored data made available, will be a licensed healthcare practitioner. Physiological data, system alarms, and patient data analysis will be made available to the user from the monitor.

Physiological data includes but is not restricted to: electrocardiograph, non-invasive blood pressure, and pulse oximetry.

Goldway UT4000A is not intended for use as an apnea monitor. Goldway UT4000A is not intended for use during MRI or CT scans.

The UT4000A is not designed for home use. The device is restricted to be used on one patient at a time.

6. Comparison with Predicate Device:

Shenzhen Goldway Industrial, Inc. has been developing and distributing physiological monitoring devices since 1995. The Substantial Equivalence of the subject device of this 510(k) notification, GoldwayUT4000A Vital Signs Monitor ("the subject device"), is claimed to Goldway Model UT4000F Patient Monitor ("the predicate device"). The predicate device is a Class II (two) device and was granted market clearance by FDA on April 11, 2003 with 510(K) control number K021154. The predicate device is designed to monitor ECG, NIBP, SpO2, IBP, ETO2, temperature, and respiration, while the subject device is for monitoring ECG, NIBP and SpO2 only. The patient data collected by the predicate device is displayed for the user on a 10.4-inch color Active TFT LCD, while the subject device is displayed on a 5.6-inch color Active TFT LCD. The packaging design of the predicate device and the subject device uses the same molded plastic. Both devices incorporate audible and visual alarm functions that are activated when set parameter limits are exceeded.

7. Discussion on Non-Clinical Tests Performed:

UT4000A meets the following standards:

- ISO 9001
- ISO 13485
- ISO 10993-1

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60878
- IEC 60601-2-27/30/34/49

- AAMI SP10

- EC 11
- EC 53

8. Discussion on Clinical Tests Performed:

Not Applicable.

9. Conclusion:

Goldway UT4000A Vital Signs Monitor has the same intended use and similar technological characteristics as Goldway Model UT4000F Patient Monitor. Moreover, the comparisons between the subject device and the predicate device demonstrate that any of the differences in their technological characteristics do not raise any questions in terms of the subject device's safety and effectiveness. Therefore, the Goldway UT4000A Vital Signs Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2004

Goldway (US), Inc.
c/o Mr. Yingchao Xiao, Esq.
Lee & Xiao Attorneys
Crestmont Building
2600 Mission Street, Suite 100
San Marino, CA 91108

Re: K033988
Trade Name: Goldway UT4000A Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: December 05, 2003
Received: December 23, 2003

Dear Mr. Xiao:

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) 594-4648. 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 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033988

Device Name: Goldway UT4000A Vital Signs Monitor

Indications For Use:

Goldway UT4000A Vital Signs Monitor is intended to monitor basic physiological parameters of patients from adults to neonates within any professional medical environment. The user, responsible to interpret the monitored data made available, will be a licensed healthcare practitioner. Physiological data, system alarms, and patient data analysis will be made available to the user from the monitor.

Physiological data includes: electrocardiograph, non-invasive blood pressure, and pulse oximetry.

Goldway UT4000A is not intended for use as an apnea monitor. Goldway UT4000A is not intended for use during MRI or CT scans.

The UT4000A is not designed for home use. The device is restricted to be used on one patient at a time.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033988