K022926 510 k summary

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

JUN - 6 2003

1.0 Submitter's Name: **GENTEEL TECHNOLOGY CO., LTD.**
Address: **3F, No. 23, Sec. 2, Chung-Hsiao E. Rd., Taipei , Taiwan, R.O.C.**

Phone: **001-886-2-23917311**
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Contact: **Mr. Deng-Jeng Chou, President**

2.0 Device Name: **GENTEEL BP-100 Wrist Blood Pressure Monitor**

3.0 Classification: Class II

4.0 Predicate Device: **GENTEEL BP-100 Wrist Blood Pressure Monitor** has similar general design with **OMRON HEM-608 Wrist Blood Pressure Monitor marketed by Omron Healthcare INC.**

5.0 Device Description: **GENTEEL BP-100 Wrist Blood Pressure Monitor** is designed to measure the systolic and diastolic blood pressure, and pulse rate(heart of an individual).

6.0 Intended Use: **GENTEEL BP-100 Wrist Blood Pressure Monitor** is intended to measure the systolic and diastolic blood pressure, and pulse rate(heart rate) by using an inflating cuff which is wrapped around the wrist. The Device is indicated for use by people over 15 age old in home use.

7.0 Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included EN-1060-3, ANSI/AAMI SP-10 and IEC 60601-1-2 requirements.
A comparison study with device that use auscultatory method was performed to validate the performance of the **GENTEEL BP-100 Wrist Blood Pressure Monitor.** The comparison study demonstrated that the clinical repeatability of **GENTEEL BP-100 Wrist Blood Pressure Monitor** is statistically and clinically acceptable.

8. Conclusions:

The **GENTEEL BP-100 Wrist Blood Pressure Monitor** have the same intended use and similar technological characteristics as **OMRON HEM-608 Wrist Blood Pressure Monitor** marketed by **Omron Healthcare INC.**. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **GENTEEL BP-100 Wrist Blood Pressure Monitor** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Genteel Technology Co., Ltd.
c/o Ms. Jennifer Reich
Harvest Consulting Corp.
3892 South America West Trail
Flagstaff, AZ 86001

Re: K022926
Trade Name: Genteel Wrist Digital Blood Pressure Monitor Model No. BP-100
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: March 11, 2003
Received: March 17, 2003

Dear Ms. Reich:

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) 594-4646. 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

510 (k) NUMBER (IF KNOWN): K022926

DEVICE NAME: **GENTEEL BP-100 Wrist Blood Pressure Monitor**
GENTEEL TECHNOLOGY CO., LTD.

INDICATIONS FOR USE:

The device is noninvasive and provide Systolic, Diastolic blood pressure and pulse rate(heart rate) mesurements by using an inflating cuff which is wrapped around the wrist. All values can be read out in one LCD Panel. The Device is indicated for use by people over 15 age old in home use.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter X
(Per 21 CFR 801.109) (Optional Format)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K022926