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EXHIBIT 2

510(k) Summary

GS Technology Co., Ltd...
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Deungchon-dong, Kangseo-Gu,
Seoul, Korea
Phone: 82-2-2668-0610
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April 22, 2003
Contact: J. S. Kim Managing Director

1. **Identification of the Device:**
   Proprietary-Trade Name: Jabes Electronic Stethoscope
   Classification Name: Electronic Stethoscope, Product code DQD
   Common/Usual Name: Electronic Stethoscope

2. **Equivalent legally marketed devices** 3M™ Littmann™ Electronic Stethoscope (K003723), Meditron stethoscope system (K991347)

3. **Indications for Use (intended use)** The JABES Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

4. **Description of the Device:** The JABES Electronic stethoscope The JABES Electronic Stethoscope is intended for use as a diagnostic aid in patients diagnosis, treatment and monitoring. It provides three filter frequency modes: Bell (20-200Hz), Diaphragm (200-500Hz), Wide (20-800Hz). Bell Mode is similar to the acoustic bell-type stethoscope and optimized for heart and other cardiology related sound. Diaphragm Mode is similar to the acoustic diaphragm-type stethoscope and optimized for higher pitched sound such as lung and bronchial sounds. Wide Mode is a combination of Bell and Diaphragm Modes. Wide Mode provides wider frequency range compare to the typical acoustic stethoscope including the Bell-type and Diaphragm-type. The JABES amplifies sounds up to 18 times bigger than an ordinary acoustic stethoscope in a broad frequency range, including a range higher than the traditional diaphragm mode. It looks similar to the traditional stethoscope including parts like a diaphragm, binaural pipes and ear tips. However, it has four (4) buttons on top of the chest set (opposite to the diaphragm side). Each of the buttons has a function of controlling the modes, volume up/down and power on/off. As an electronic stethoscope, it needs two (2) batteries (AAA type, 1.5V) to operate. The stethoscope has power saving functions for longer battery life and has a low battery indicator to prevent the use in malfunctioning condition due to the low power.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Device name	Predicate Device		New Device
	3M Littmann Electronic stethoscope, Model 4000(k003723)	Meditron stethoscope system(K9913647)	JABES electronic stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	3M	MEDITRON AS	GS Technology Co., Ltd
Frequency Response Mode	Bell(20-200Hz), Diaphragm(100-500Hz) Extended range(20-1,000Hz)	Bell(20-600Hz), Diaphragm(200-20000Hz) Extended range(20-20000Hz)	Bell(20-200Hz), Diaphragm(200-500Hz) Extended range (20-800 Hz)
Amplification	Up to 18 times amplification	Up to 30 times amplification	Up to 18 times amplification
Display heart rate	Yes	No	Yes
Permits data transfer of stored digital signal to and from IBM-Compatible PC	None	Yes	Yes
Maximum sound level	140dB SPL Max	100dB SPL Max	With in 120dB SPL Max
Volume control	8 Steps Volume control	Continuous variable	12 Steps Volume control
Energy source	Two(2) AAA alkaline batteries	One(1) 1/2 AA Lithium battery	Two(2) AAA alkaline batteries
Manual On/Off button Automatic shut-off By electronics	Yes	Yes	Yes
Low Battery Indicator	Yes	No	Yes

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of GS Technology Co. Ltd, that the Jabes Electronic is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2003

GS Technology Co., Ltd.
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K031446
Trade Name: JABES Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: August 4, 2003
Received: August 6, 2003

Dear Mr. Kamm:

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

i) Indications for Use

510(k) Number K031446

Device Name: Electronic stethoscope (Model: JABES)
Indications for Use: The JABES Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031446