K100427
p 1/3

MAY 28 2010

510 (k) Summary

1. Submitter Information

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Date Prepared	February 5th, 2010

2. Name of Device

Trade Names	FORA GW 9014 TeleHealth Gateway / TD-9014 TeleHealth Gateway
Common Names	Telemedicine System
Classification Names and Regulations	Radiofrequency Physiological Signal Transmitter and Receiver Class II 21 CFR 870.2910

3. Predicate Device

Trade/Proprietary Name:	RTX3320 Wireless TeleHealth Gateway
Common/Usual Name:	Physiological Transmitter and Receiver
Submitter	RTX Healthcare A/S
510 (k) Number	K041816

K100427
p 2/3

4. Device Description

FORA GW 9014/TD-9014 TeleHealth Gateway serves as the communication link between various compatible monitors and the compatible healthcare facility remotely. The healthcare facility may include healthcare providers, physicians, other caregivers, or a disease management center.

The proposed device uses either RS232 cable or Bluetooth connection to receive data from the monitors and then transmit the collected data to the server system through either Ethernet or modem. The healthcare providers can view the patient's test results through the web server at any time.

5. Intended Use

The FORA GW 9014/TD-9014 TeleHealth Gateway is for use by patients at home or at clinical settings. It is intended to be used in combination with a variety of patient monitors upon the prescription of a licensed physician or other authorized healthcare provider. It serves as the remote communication link between various FDA-cleared compatible monitors and the compatible healthcare facility at another location. The healthcare facility could be with the healthcare provider, or at a disease management center, or other out-of-hospital caregivers.

This device is intended to transmit selected medical information (i.e. blood glucose, blood pressure, body weight, body temperature, body fat, and body hydration) measured by FDA approved medical devices via RS232 or wireless connections over the internet or residential telephone line.

This device does not measure, interpret or make any decisions on the data that it conveys.

This device is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time critical data.

This device is not for use in systems which substitute for medical care, or for patients requiring direct medical supervision.

This device is not intended for patients requiring direct medical supervision or emergency intervention. Clinical judgment and experience are required to check and interpret the measurements collected and transmitted.

K100427
#3/3

6. Comparison to Predicate Device

The FORA GW 9014/TD-9014 TeleHealth Gateway is substantially equivalent to the RTX3320 Wireless TeleHealth Gateway (K041816).

7. Performance Studies

Software validation of FORA GW 9014/TD-9014 TeleHealth Gateway and indicates that the proposed device meets the acceptable criteria.

The FORA GW 9014/TD-9014 TeleHealth Gateway meets the requirements of IEC/EN 60601-1, EN 300 328, EN 301 489-17 V1.2.1:2002, and EN 301 489-1 V1.8.1:2008, IEC 61000-4-2, etc.

The consumer study shows the instruction manual of FORA GW 9014 / TD-9014 TeleHealth Gateway is understandable for lay users.

8. Conclusion

FORA GW 9014/TD-9014 TeleHealth Gateway demonstrates satisfactory performance and is suitable for its intended use. FORA GW 9014/TD-9014 TeleHealth Gateway is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

TaiDoc Technology Corporation
c/o Mr. Teling Hsu
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd. Rd., Wugu Township
Taipei County
CHINA (TAIWAN) 24888

MAY 2 8 2010

Re: K100427
Trade/Device Name: FORA GW 9014 TeleHealth Gateway/TD-9014 TeleHealth Gateway
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: April 19, 2010
Received: April 19, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

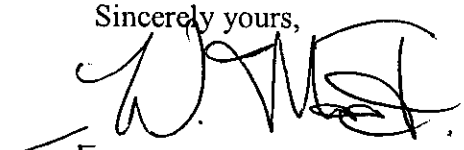
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K100427

Indications for Use

510(k) Number: k100427

Device Name: FORA GW 9014 TeleHealth Gateway / TD-9014 TeleHealth Gateway

Indications for Use:

The FORA GW 9014/TD-9014 TeleHealth Gateway is for use by patients at home or at clinical settings. It is intended to be used in combination with a variety of patient monitors upon the prescription of a licensed physician or other authorized healthcare provider. It serves as the remote communication link between various FDA-cleared compatible monitors and the compatible healthcare facility at another location. The healthcare facility could be with the healthcare provider, or at a disease management center, or other out-of-hospital caregivers.

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This device is not intended for patients requiring direct medical supervision or emergency intervention. Clinical judgment and experience are required to check and interpret the measurements collected and transmitted.

Prescription Use ___X___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100427