K083046
p1/3

Attachment 8

JAN 16 2009

510 (k) Summary

1 Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Yuhua Chen
Address	6F, No 127, Wugong 2nd Rd , Wugu Township, Taipei County, 248, Taiwan
Phone	(886-2) 6625-8188
FAX	(886-2) 6625-0288
E-mail	yuhua chen@taidoc com
Date Prepared	October 9th, 2008

2 Name of Device

Trade Names	FORA TeleHealth System
Common Names	Telemedicine system
Classification Names and Regulations	a) Radiofrequency physiological signal transmitter and receiver, Class II, 21CFR870 2910 b) Glucose Test System, Class II, 21CFR862 1345 c) Noninvasive Blood Pressure Measurement System, Class II, 21CFR870 1130,

3 Predicate Device

Trade/Proprietary Name	Carematix Wellness System
Common/Usual Name	Telemedicine system
Submitter	Carematix, Inc
510 (k) Number	K031840
Trade/Proprietary Name system	BL Healthcare Remote Care Management
Common/Usual Name	Telemedicine system
Submitter	BL Healtheare, Inc
510 (k) Number	K051470

K083046
p2/3

4 Device Description

FORA TeleHealth System serves as the communication link between FDA approved compatible devices and the server software at a compatible healthcare facility The healthcare facility may include healthcare professionals, other caregivers, or a disease management center

The system is intended to gather and transmit patient data such as blood glucose, blood pressure and pulse rate via cable or wireless connections from patient to healthcare professionals at another facility The transmitted patient data is able to be reviewed and analyzed in this system Through evaluation of the historical test results, home users and healthcare professionals can do health management effectively

5 Intended Use

The FORA TeleHealth System is intended for use by patients remotely in combination with a variety of monitoring devices upon the prescription of healthcare professionals The FORA TeleHealth System serves as the communication link between the FDA approved compatible devices and the server software at a compatible healthcare facility The healthcare facility may include healthcare professionals, other caregivers, or a disease management center

The system is intended to gather and transmit patient data such as blood glucose, blood pressure and pulse rate via cable or wireless connections from patient to healthcare professionals at another facility The transmitted patient data is able to be reviewed and analyzed in this system Through evaluation of the historical test results, home users and healthcare professionals can do health management effectively

The FORA TeleHealth System may not be used as a substitute for direct medical intervention or emergency care Interpretation of the information collected and transmitted requires clinical judgment by an appropriate healthcare professional

This system is to be used or prescribed on the order of a physician

K083046
p 3/3

6 Comparison to Predicate Device

The FORA TeleHealth System is substantially equivalent to the Carematix Wellness System (K031840) and BL Healthcare Remote Care Management system (K051470)

7 Performance Studies

Testing of FORA TeleHealth System and user evaluation indicate that the system meets the acceptable criteria

8 Conclusion

FORA TeleHealth System demonstrates satisfactory performance and is suitable for its intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 5 - 2009

TaiDoc Technology Corporation
c/o Ms. Yuhua Chen
Assistant Manager
6F, No. 127, Wugong 2nd Rd.,
Wugu, Taipei County
China Taiwan 248

Re: K083046
Trade/Device Name: FORA TeleHealth System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: November 27, 2008
Received: December 1, 2008

Dear Ms. Chen:

This letter corrects our substantially equivalent letter of January 16, 2009.

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 (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 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 continue 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 (240) 276-0120. 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 (240) 276-3150 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

K083046

Attachment 1

Indications for Use

510(k) Number K083046

Device Name FORA TeleHealth System

Indications for Use

The FORA TeleHealth System is intended for use by patients remotely in combination with a variety of monitoring devices upon the prescription of healthcare professionals The system serves as the communication link between the FDA approved compatible devices and the server software at a compatible healthcare facility The healthcare facility may include healthcare professionals, other caregivers, or a disease management center

The system is intended to gather and transmit patient data such as blood glucose, blood pressure and pulse rate via cable or wireless connections from patient to healthcare professionals at another facility The transmitted patient data is able to be reviewed and analyzed in this system Through evaluation of the historical test results, home users and healthcare professionals can do health management effectively

The FORA TeleHealth System may not be used as a substitute for direct medical intervention or emergency care Interpretation of the information collected and transmitted requires clinical judgment by an appropriate healthcare professional

This system is to be used or prescribed on the order of a physician

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) 11/16/09
Division of Cardiovascular Devices

510(k) Number K083046