K061452

510(k) Summary

JUL 12 2006

Submitter's Information

Submitter's Name:	TUNG FU ELECTRIC CO., LTD.
Contact person:	Shu-Mei Wu, Ph.D.
Address:	No.11, Shin Chung Road, An Ping Industrial District, Tainan, CHINA (TAIWAN) 70252
Phone:	+886-6-2617105
Fax:	+886-6-2633822
E-mail:	shumei@taidoc.com.tw
Date Prepared:	May 8, 2006

1. Device

Trade Name: TF-BP01™ Blood Pressure Monitor
Common Name: Noninvasive Blood Pressure Measurement System
Classification Name: blood pressure monitor
Class II devices, 21 CFR 870.1130
Product Code: DXN

2. Predicate Device

Trade /Proprietary Name: CLEVER TD-3018A Blood Pressure Monitor, TD-3018A
Common Name: Noninvasive Blood Pressure Measurement System
Classification Name: blood pressure monitor
Class II devices, 21 CFR 870.1130
Manufacturer: TaiDoc Technology Corporation
510 (k) Number: K051703

3. Device Description

The TF-BP01™ Blood Pressure Monitor is a wrist blood pressure monitor and uses the oscillometric method to measure the blood pressure. The device includes setting button, function button, LCD display, start/stop button, recall memory button, and

wrist cuff.The symbols display on LCD include month, date, hour, minute, systolic rate, diastolic rate, pulse rate, pulse symbol, blood pressure unit, battery display, error symbol, memory record.

Both devices determine values of blood pressure by using oscillometric method. In this method, pulse waves are detected by using pressure sensors. Then the diastolic blood pressure, mean average pressure, and pulse pressure are derived. Furthermore, the systolic blood pressure and pulse rate are computed based on the information.

4. Intended Use

The intended use of TF-BP01™ Blood Pressure Monitor is to measure human systolic, diastolic blood pressure and heart rate by using the oscillometric method. The measurement position of the device is the wrist of the subject.

5. Technology Characteristics Comparison

Both devices determine values of blood pressure by using oscillometric method. In this method, pulse waves are detected by using pressure sensors. Then the diastolic blood pressure, mean average pressure, and pulse pressure are derived. Furthermore, the systolic blood pressure and pulse rate are computed based on the information.

6. Non-clinical Performance

The results for non-clinical trials as presented in this document demonstrated the conformance to the SP10 standard that is also the reference standard for the predicate device. Therefore, the substantial equivalence between the devices is determined.

7. Clinical Performance

As the predicate device, the clinical test results of the TF-BP01™ showed the functions of the device met the criteria in the SP10 standard. Hence, it is reasonable to conclude the substantial equivalence between the devices.

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8. Conclusions

The TF-BP01™ Blood Pressure Monitor 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

JUL 12 2006

Tung Fu Electric Co., Ltd.
c/o Dr. Shu-Mei Wu
Project Manager
Taidoc Technology Corporation
4F, No. 88, Sec 1, Kwang Fu Road
San Chung, Taipei Hsien 241
TAIWAN

Re: K061452
Trade Name: TF-BP01™ Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 8, 2006
Received: May 25, 2006

Dear Dr. Wu:

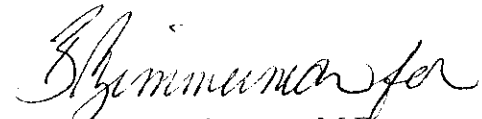
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (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/industry/support/index.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: K061452

Device Name: *TF-BP01™* Blood Pressure Monitor

Indications For Use:

"The *TF-BP01™* blood pressure monitor is intended for use in the home to measure systolic and diastolic blood pressures and pulse rate on adults aged 18 and older. Measurements are obtained using a non-invasive technique by placing an inflatable cuff around the wrist. The cuff circumference is 5.25 to 7.75 inches."

Prescription Use _____ AND/OR Over-The-Counter Use ___X__

(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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061452