K111141

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FEB 2 1 2012

BOKANG 温州市博康仪表有限公司
BOKANG INSTRUMENTS CO.,LTD

510(K) Summary

Contact Johnny Cao and Jack Cheng
Hangzhou Gainder Enterprises Administration Consulting Co., Ltd
Room 1623,Block B, No.83 north Qiutao Road, Hangzhou,310016
P.R.China
Tel: +86-571-86984378
Fax: +86-571-89265351

Submitter Xiang Youwang
Wenzhou Bokang Instruments Co.,Ltd
Haining road, Haibin Longwan, Wenzhou, Zhejiang 325024
P.R.China
Tel:+86-577-86876969
Fax:+86-577-86880123

Proprietary Name Bokang Digital Blood Pressure Monitor, Model BK6001, Model BK6002 and Model BK6023

Common Name Noninvasive blood pressure measurement system.
Classification Name Noninvasive blood pressure measurement system.

Panel Cardiovascular

Classification

classification name	21 CFR section	Product code	Class
Noninvasive blood pressure measurement system.	870.1130	DXN	II

Predicate Device
A & D LifeSource UA-704 Digital Blood Pressure Monitor (K032499)
Bioland Blood Pressure Monitor Model 2001, 2003, 3000 (K083681)

Description and Indication for Use
Bokang Digital Blood Pressure Monitor are non-invasive blood pressure (NIBP) monitors which use a standard oscillometric measurement method and intend for noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate for adults only.

Model BK6001 is a semi-auto digital non-invasive blood pressure monitors which respectively use an inflation cuff wrapped around the upper arm. The cuff is inflated by a manual air pump.
Model BK6002 is an automatic digital non-invasive blood pressure monitors which respectively use an inflation cuff wrapped around the upper arm. The cuff is inflated automatically by an electrical air pump.
Model BK6023 is a wrist automatic digital non-invasive blood pressure monitors which respectively use an inflation cuff wrapped around the wrists. The cuff is inflated automatically by a electrical air pump.

The systolic, diastolic blood pressures and heart beats are transmitted via air pressure in the inflated cuff to transducer for the determination with oscillometric method. The cuff integrated with bladder is inflated by air pump. The deflation rate is controlled rapidly and automatically released by a electric valve at a constant rate after the measurement. The measurement results including diastolic, systolic pressure and heart pulse rate are displayed on the LCD. Besides the real-time display, the blood pressure and pulse values are also averaged, stored, and recalled from the last data.

Performance
Bokang Digital Blood Pressure Monitors have been tested to meet the requirement of ANSI/AAMI SP-10 standard and FDA guidance "Non-invasive Blood Pressure Monitor Guidance"

Substantial Equivalency
After analyzing both bench and clinical testing data, it is the conclusion of Bokang Digital Blood Pressure Monitor, Model BK6001, Model BK6002 and Model BK6023 are substantial equivalent to the predicate device, A & D LifeSource UA-704 Digital Blood Pressure Monitor (K032499) and Bioland Blood Pressure Monitor Model 2001, 2003, 3000 (K083681).

Discussion of Clinical Tests Performed:
Controlled human clinical studies were conducted using the Bokang Digital Blood Pressure Monitor, Model BK6001, Model BK6002 and Model BK6023. Clinical data was presented which evaluated clinical bias, clinical uncertainty and clinical repeatability per the Bokang Clinical Test Protocol outline and meet the requirement of AAMI SP10.

Conclusions:
Bokang Digital Blood Pressure Monitor, Model BK6001, Model BK6002 and Model BK6023 have the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, Bokang Digital Blood Pressure Monitors are substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Wenzhou Bokang Instruments Co., Ltd.
c/o Mr. Xiang Youwang
President
Haining Road
Haibin Longwan Zone
Wenzhou, Zhejiang 325024
P.R. China

Re: K111141
Trade/Device Names:
Bokang Semi-auto Digital Blood Pressure Monitor, Model BK6001
Bokang Automatic Digital Blood Pressure Monitor, Model BK6002
Bokang Wrist Digital Blood Pressure Monitor, Model BK6023
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: Undated
Received: February 8, 2012

Dear Mr. Xiang:

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

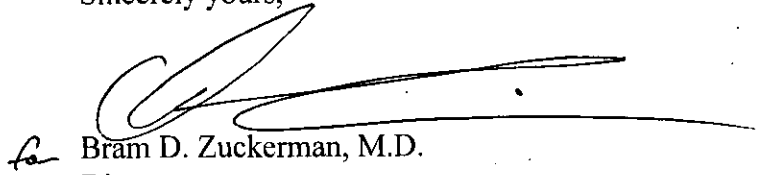
adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 limpited 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

Indications For Use Form

510(k) Number (if known): K111141

Device Name:

Indications for Use:

Bokang Digital Blood Pressure Monitor, Model BK6001, Model BK6002 and Model BK6023 are non-invasive blood pressure (NIBP) monitors which use a standard oscillometric measurement method and intend for noninvasive measurement of systolic and diastolic blood pressure and determination of pulse rate by using an inflating cuff which is wrapped around the upper arm or wrist. The device is indicated for use in adults only.

Prescription Use _____	AND/	Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D)	OR	(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111141