JAN 13 2005

510(K) Summary

Contact Zhen Hui
Zhejiang ML Medical Device Consultant Co.,Ltd
23#,Huanchengdong Road,Hangzhou,310009
P.R.China
Tel:+86-571-87044795
Fax:+86-571-87046982

Submitter Xiang Youwang
Wenzhou Bokang Instrument Co.,Ltd
72#,Haibin Ningchen Hengjie,Wenzhou,325024
P.R.China
Tel:+86-577-86873588
Fax:+86-577-86880123

Proprietary Name Aneroid Sphygmomanometer BK2002

Common Name Aneroid Sphygmomanometer BK2002

Classification Name Blood Pressure,Cuff

Panel Cardiovascular

Classification The classification Name,21 CFR Part and Paragraph number,Product code and classification of Aneroid Sphygmomanometer BK2002 and stethoscope are as follows.The tier categorization is also included.

classification name	21 CFR section	Product code	Class	Tier
Blood Pressure,Cuff	870.1120	DXQ	II	2
Stethoscope	870.1875 (optional)	LDE	I (exempt)	I

Predicate Device The Bokang's Aneroid Sphygmomanometer BK2002 is substantially equivalent to Nihon Seimitsu Sokki Co.,Ltd's model HT-110 which 510(K) number is K012194

Device Description The device comproses tubing attached to a soft ineastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive sphygmomaniometer.

Indication For Use	The device is intended to be used by medical professionals or in the home for the measurement of systonic and diastonic pressure on adults.The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.
Thchnological Characteristics	The Bokang's Aneroid Sphygmomanometer BK2002 is virtually the same as Nihon Seimitsu Sokki Co.,Ltd's model HT-110
Performance	The Aneroid Sphygmomanometer BK2002 has been tested to conform to the ANSI/AAMI standard SP-9,Non-automated sphygmomanometer.
Conclusion	In accordance with the Federal Food,Drug and Cosmetic Act,21CFR Part 807 and based on the information provided in this premarket notification,Wenzhou Bokang Instrument Co.,Ltd concludes that the Aneroid Sphygmomanometer BK2002 is safe and effective,and substantially equivalent to the predicate device described herein.
Others	Wenzhou Bokang Instrument Co.,Ltd will update and include in this summary any other informations needed by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

Wenzhou Bokang Instrument Co. Ltd.
c/o Mr. Tzu-Wei Li
Manager
Center for Measurement Standards/Industrial
Technology Research Institute
Bldg. 16, 321 Kuang Fu Rd.
Sec. 2 Hsinchu, Taiwan 30042
R.O.C

Re: K043286
Trade Name: Aneroid Sphygmomanometer BK2002
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: December 29, 2004
Received: January 05, 2005

Dear Mr. Li:

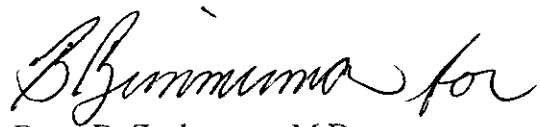
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

K043286/

RE: Review of BK2002 – OMDE 930705
BY: Sandy Liu
DA: 01/03/05

510(k) Number (if known): K043286

Device Name: Aneroid Sphygmomanometer BK2002

Indications For Use:

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

Prescription Use_____ OR Over-The-Counter Use__V___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON NOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K043286
(Division Sign-Off)
Division of Cardiovascular Devices
510(K) Number