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Attachment II 510(k) Summary

A required by 21 CFR 807.92

The assigned 510(k) number is: K102825

Date of Preparation	September 28, 2010
510(k) Sponsor	APK Technology Co., Ltd, Registration #: 3007699081 504, C6 Building, Hengfeng Industry, Hezhou, Xixiang, Baoan District, Shenzhen, Guangdong, 518126, China Contact Person: Cindy Chan Tel: 86-755-27325581 Fax: 86-755-27325585 Email: cindy@apk-technology.com
Submission Correspondent	Mr. Lee Fu Mid-Link Consulting Co., Ltd P.O. BOX 237-023, Shanghai, 200237, China T: +86-21-22815850 | F: 240-238-7587
Proposed Device	Device Trade Name: Blood Pressure Cuff; Classification: Class II | DXQ | 21 CFR 870.1120;
Intended Use	Blood Pressure Cuffs, include reusable and disposable, are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to determine blood parameters on neonate, pediatric and adult patients.

Additional Information I for K102825 Blood Pressure Cuff –Attachment II 510(k) Summary

Device Description

The proposed device, Blood Pressure Cuff, is a rectangle soft inelastic sleeve. Some types are disposable without a bladder; some are reusable with a bladder or without a bladder. There is a single-tube or twin-tube connected to the bladder and the NIBP measurement device for inflating and deflating. It is available in various sizes for different arm range. It is provided non-sterile and each cuff. It is used in conjunction with NIBP Monitor System.

Models:

Model	Intended Arm Range (Unit: cm)	Disposable	Reusable
A-XT-12D(1)	3.3-5.6	X	
A-XT-12D(2)	4.2-7.1	X	
A-XT-12D(3)	5-10.5	X	
A-XT-12D(4)	6.9-11.7	X	
A-XT-12D(5)	8.9-15	X	
A-XT-12D(7)	9.8-13.3	X	
A-XT-09D(8)	12.4-16.8	X	
A-XT-08D(9)	15.8-21.3	X	
A-XT-08D(10)	20-27	X	
A-XT-07D(11)	25.3-34.3	X	
A-XT-10D(12)	32.1-43.4	X	
A-XT-11D(13)	44-66	X	
A-XT-07	25-35		X
A-XT-08	18-26		X
A-XT-09	10-19		X
A-XT-10	33-47		X
A-XT-11	44-66		X
A-XT-12	6-11		X
A-XT-12W(1)	3.3-5.6		X
A-XT-12W(2)	4.2-7.1		X
A-XT-12W(3)	5-10.5		X
A-XT-12W(4)	6.9-11.7		X
A-XT-12W(5)	8.9-15		X
A-XT-12W(7)	9.8-13.3		X
A-XT-09W(8)	12.4-16.8		X
A-XT-08W(9)	15.8-21.3		X
A-XT-08W(10)	20-27		X
A-XT-07W(11)	25.3-34.3		X
A-XT-10W(12)	32.1-43.4		X
A-XT-11W(13)	40.7-55		X

Testing Summary	The device was tested per ISO 10993 series standards to evaluate its biocompatibility and AAMI SP10:2002+A1:2003+A2:2006.
SE Conclusion	The proposed devices, Blood Pressure Cuff, are claimed to be Substantially Equivalent (SE) to the predicate devices, Disposable Blood Pressure Cuff, K08085 and Tytan Blood Pressure Cuff, K062238.

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

APK Technology Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023
Shanghai 200237
CHINA

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Re: K102825
Trade/Device Name: Disposable Blood Pressure Cuff
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood-Pressure Cuff
Regulatory Class: II (two)
Product Code: 74 DXQ
Dated: January 25, 2011
Received: January 28, 2011

Dear Ms. Hong:

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 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

K102825

Attachment I Indication for Use Statement

510(k) Number: K102825
Device Name: Blood Pressure Cuff

Indications for Use:

Blood Pressure Cuffs, include reusable and disposable, are intended to be wrapped on the upper arm and used with a non-invasive blood pressure monitor system to determine blood parameters on neonate, pediatric and adult patients.

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

for B Zuckerman

(Division Sign-Off) 3/2/2011
Division of Cardiovascular Devices
510(k) Number K102825