



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 14, 2016

Ningbo Free Trade Zone Tenso Medical Instruments Co., Ltd.
% Charles Shen
Official Correspondent
Manton Business And Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K153251

Trade/Device Name: Tenso TS-101S and TS-101D Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: March 8, 2016
Received: March 8, 2016

Dear Charles Shen:

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 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored FDA logo watermark.

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

510(k) Number (if known)

K153251

Device Name

TS-101S and TS-101D Disposable Blood Pressure Cuff

Indications for Use (Describe)

The Tenso TS-101S and TS-101D disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in infant, pediatric and adult sizes. They are used in hospital settings.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Ningbo Free Trade Zone Tenso Medical Instruments Co., Ltd.
24/F, 238 Zhongshan East Road, Ningbo, China. Zipcode 315010
TEL: (086) 574-87344400
Submitter's FDA Registration Number: N/A

5.2 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey, USA 07436
Tel: 608-217-9358
Email: cyshen@aol.com

5.3 Date of Summary: November 09, 2015

5.4 Device Name:

Proprietary Name:	Tenso TS-101S and TS-101D Disposable Blood Pressure Cuff
Common Name:	Blood Pressure Cuff
Classification Name:	Blood Pressure Cuff
Device Classification:	II
Classification Regulation:	21 CFR 870.1120
Panel:	Cardiovascular
Product Code:	DXQ

5.5 Predicate Device Information:

- (1) K151290, "Disposable/Reusable Blood Pressure Cuff", manufactured by "Xuzhou Maicuff Technology Co., Ltd." (for arm cuffs)
- (2) K120364, "Unined Disposable Blood Pressure Cuff", manufactured by "Unined Medical supplies Inc." (for thigh cuffs)

5.6 Device Description:

"Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs" are an accessory used in conjunction with noninvasive blood pressure measurement systems. They incorporate an inflatable nondistensible bladder, sized to encircle a patient's limb. This allows air to

flow in and out of the cuff for inflation and deflation, for the purpose of occlusion of an artery.

“Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs” have a structure which contains Cuff with bladder and Air Hose. Air hose has either single tube or double tubes.” The device is secured by hook and loop closure onto the patient limb. It has two variations: TS-101S” is the variant that has single tube structure, while “TS-101D” is the variant that has double-tube structure.

The cuff is made from non-woven fabrics, the air hose and tubes are made from polyvinyl chloride. Therefore, the non-woven fabric (cuff) is the material used to contacting with the patient.

“Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs” are single use device and are provided as non-sterile. They are available in infant, pediatric and adult sizes.

“Tenso TS-101S Disposable Blood Pressure Cuffs” (single tube model) have 6 models with different size for different population with different arm size. “TS-101D Disposable Blood Pressure Cuffs” (double tube model) also have 6 models with different size for different population with different arm size.

5.7 Intended Use:

Tenso TS-101S and TS-101D disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in infant, pediatric and adult sizes. They are used in hospital settings.

5.8 Summary of Device Testing:

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 81060-1:2007 Non-Invasive Sphygmomanometers - Part 1: Requirements And Test Methods For Non-Automated Measurement Type

The subject device also conforms to the following FDA guidance:

- Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final

Specifically, the following table summarizes the mechanical testing results of the subject device:

Characteristics	Specifications	Test Method	Results
Mechanical Strength	Able to withstand 300 mm Hg	Internal	Meet
Fatigue Strength	Able to withstand inflation (to 300 mm Hg) and deflation for at least 300 times	Internal	Meet
Leakage Rate	Leakage rate < 4 mm Hg / Minute	ISO 81060-1	Meet

5.9 Technological Comparison with Predicate Device

The following tables show similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing (Arm Cuffs)

Description	Subject Device	Predicate Device (K151290)
Indication for Use	Tenso TS-101S and TS-101D disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in infant, pediatric and adult sizes. They are used in hospital settings.	The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.
Patient Population	Adults/Pediatrics	Adults/Pediatrics
Tube Configuration	One or two tube	One or two tube
Material	Non-woven, nylon, and PVC	Non-woven, nylon, and PVC
Size	Conform to AHA bladder sizes recommendations Infant (10-14 cm) Pediatric (14-20 cm) Small Adult (20-26 cm) Adult (25-35 cm) Large Adult (33-47 cm)	Conform to AHA bladder sizes Recommendations Neonatal 1 (3-5.5 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm) Infant (9-14.5 cm) Pediatric (13-21.5 cm) Small Adult (21-27 cm) Adult (26-35.5 cm) Large Adult (35-45 cm)
Single Use	Yes	Yes

Sterile	Non-sterile	Non-sterile
Pressure Range	0-300 mm Hg	0-300 mm Hg
Measurement Range	0-270 mm Hg	0 - >260 mm Hg

Table 5.2: Comparison of Intended Use, Design, Material, and Processing (Thigh Cuffs)

Description	Subject Device	Predicate Device (K120364)
Indication for Use	Tenso TS-101S and TS-101D disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in infant, pediatric and adult sizes. They are used in hospital settings.	The Unimed Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.
Patient Population	Adults/Pediatrics	Adults/Pediatrics
Tube Configuration	One or two tube	One or two tube
Material	Non-woven, nylon, and PVC	Non-woven, nylon, and PVC
Size	Conform to AHA bladder sizes recommendations Thigh (45-66 mm)	Conform to AHA bladder sizes Recommendations Thigh (45-56 mm)
Single Use	Yes	Yes
Sterile	Non-sterile	Non-sterile
Pressure Range	0-300 mm Hg	0-300 mm Hg
Measurement Range	0-270 Hg	0 - >260 mm Hg

The subject device is essentially identical to the predicate devices in terms of indications for use, design, and material. The minor differences are not related to the safety and efficacy features of the two devices.

5.10 Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 81060-1, and results met all relevant requirements in the test standard.

The following table shows similarities and differences of the biocompatibility between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the FDA recognized consensus standard of ISO 10993, and results met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.2: Comparison of Biocompatibility Testing

Description	Subject Device:	Predicate Device (K151290)
Cytotoxicity (ISO 10993-5:2009)	No cyteotoxicity effect	No cyteotoxicity effect
Irritation (ISO 10993-10: 2010)	Not a irritant under the conditions of the study	Not a irritant under the conditions of the study
Sensitization (ISO 10993-10: 2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study

Therefore, “Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs” manufactured by “Ningbo Free Trade Zone Tenso Medical Instruments Co., Ltd.” meet requirements per ISO 81060-1 and ISO 10993-1. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses. The test results are also comparable to the predicate device.

5.11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that “Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs” and their predicate devices have the identical indications for use, similar composition and biocompatibility, and similar performance.

The difference between the “Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs” and their predicate devices do not raise any question regarding its safety and effectiveness.

“Tenso TS-101S and TS-101D Disposable Blood Pressure Cuffs”, as designed and manufactured, are as safe and effective as its predicate device, and therefore is substantially equivalent as its predicate device.