biocomfort

510(k) Summary

The assigned 510(k) number is: K081498

DEC 17 2008

Date Prepared: May 19, 2008

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US Agent (Contact):
Mr. Dieter Schill
President
Biocomfort Inc.
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Burlington, MA 01803 USA
Phone: +1 866 294 8267
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Device Trade Name:	tenso-comfort BPM 105 / 205
Common Name:	Blood pressure meter
Device Classification Name:	System, Test, Non- invasive Blood Pressure meter, Over The Counter
Product Code:	DXN
Device Classification No.:	Part 870.1130
Regulatory Status:	Class II

Predicate Devices:	Clever TD-3018A
Device Trade Name:	Clever TD-3018A
510(k) Number:	K051703
Device Classification Name:	Blood pressure meter, Over The Counter
Product Code:	DXN
Device Classification No.:	Part 870.1130
Regulatory Status:	Class II

Device Description:
The non-invasive wrist blood pressure meter BPM105 and BPM205 determine the arterial blood pressure by means of the oscillometric blood pressure measuring method. With this method the pressure fluctuations are measured, which develop when depressing pulse-cyclic blood pulses in the compressed arteria under the blood pressure cuff put on. The blood pressure apparatus in the model variant BPM105 is equipped with a radio module, with which the transmission of the stored

measured values on a PC is optionally possible (radio interface for PC and software is offered as accessory).

Intended Use:

The tenso-comfort BPM 105 /BPM 205 is a wrist non-invasive blood pressure device which is intended for use in measuring blood pressure and pulse rate in adult patient population. The measuring method is an oscillometric blood pressure measurement with automatic sequence and refers to the auscultatory method as the reference standard.
The model version BPM 105 is equipped with a radio module to transmit the measurement data to a PC.
The device is not intended for neonatal use..

SE Discussion:

		Substantial Equivalent Device	Predicate Devices	
		Biocomfort tenso-comfort BPM 105/ BPM 205	**TaiDoc Clever TD-3018A**	**Discussion of differences**
[01]	**Indication for use**	The tenso-comfort BPM 105 /BPM 205 is a wrist non-invasive blood pressure device which is intended for use in measuring blood pressure and pulse rate in adult patient population. The measuring method is an oscillometric blood pressure measurement with automatic sequence and refers to the auscultatory method as the reference standard. The model version BPM 105 is equipped with a radio module to transmit the measurement data to a PC.	The Clever TD-3018A Blood Pressure Monitor provide intended to use non-invasive measure the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25"~ 7.75".	The BPM 105 is equipped with a transmitter to send the measuring results to a PC.
[02]	**Target population**	Adults, Lay users	Adults Lay users	Equivalent
[03]	**Measuring principle**	Oscillometric method	Oscillometric method	Equivalent
[04]	**Type of results**	Pressure: mmHg Puls: beats/minute	Pressure: mmHg Puls: beats/minute	Equivalent
[05]	**Presentation of results**	LCD Digital Display	LCD Digital Display	Equivalent
[06]	**Measurement range**	Pressure: 0 – 300 mmHg Pulse: 40 – 199 beats/minute	Pressure: 0 – 300 mmHg Pulse: 40 – 199 beats/minute	Equivalent
[07]	**Measuring accuracy**	Pressure: ±3 mmHg Pulse: ±5% of the value	Pressure: ±3 mmHg or 2% of reading Pulse: ±4% of the reading	In the same area and considered equivalent

		Substantial Equivalent Device	Predicate Devices	
		Biocomfort tenso-comfort BPM 105/ BPM 205	**TaiDoc Clever TD-3018A**	**Discussion of differences**
[08]	**Inflation**	Automatic inflation	Automatic inflation	Equivalent
[09]	**Deflation**	Electric Valve	Electric Valve	Equivalent
[10]	**Pressure release**	Automatic exhaust valve	Automatic exhaust valve	Equivalent
[11]	**Pressure detection**	Piezo-resistive silicon pressure transducer	Piezo-resistive silicon pressure transducer	Equivalent
[12]	**Measuring period**	App. 30 seconds	App. 20 seconds	Equivalent
[13]	**Operation environment**	10°C – 40°C 50°F – 104°F	10°C – 40°C 50°F – 104°F	Equivalent
[14]	**Storage environment**	-20°C – 60°C -4°F – 140°F 10% - 95% relative humidity	-20°C – 60°C -4°F – 140°F 10% - 95% relative humidity	Equivalent
[15]	**Battery life**	App. 300 measurements	App. 200 uses	Improved energy management and considered equivalent
[16]	**Cuff size**	135mm – 220mm 5 ¼ in – 8 ⅔ in	135mm – 195mm 5 ¼ in – 7 ¾ in	Slightly larger cuff and considered equivalent
[17]	**Dimensions**	70 x 90 x 26 mm	76 x 64 x 29 mm	Slightly different dimension due to corporate design. The devices are considered equivalent.
[18]	**Weight**	Ca. 140 g (without batteries)	132 g (with batteries)	Equivalent
[19]	**Mobility**	Hand-held	Hand-held	Equivalent
[20]	**Memory Capability**	110 measurements per user (up to 8 users) with date and time	352 sets of reading with date and time	Different number of measurement due to the user management. It is considered equivalent.
[21]	**Power supply**	Two 1.5 alkaline batteries type AAA/LR03	Two 1.5 alkaline batteries type AAA/LR03	Equivalent
[22]	**Connectivity**	Wireless interface with 2.4 GHz according to IEEE802.15.4, with 10 m indoor range	None	The model BPM 105 provides the option to communicate via wireless technology to a PC which is set up for the interface protocol.

Discussion of the Substantial Equivalence Decision:
The only difference between the BPM 105/205 and the predicate device is the ability to communicate with a PC via wireless connection. This feature does neither affect nor even represent the measurement of the blood pressure. The wireless connection is for the upload of measurement data and the set up of basic device functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Mr. Dieter Schill
President
Biocomfort Inc.
23 Third Avenue
Burlington, MA 01803

Re: K081498
Trade/Device Name: tenso-comfort BPM 105/205
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: December 12, 2008
Received: December 17, 2008

Dear Mr. Schill:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

biocomfort

Indications for Use

510(k) Number (if known): K081498

Device Name: tenso-comfort BPM 105 / 205

The tenso-comfort BPM 105 /BPM 205 is a wrist non-invasive blood pressure device which is intended for use in measuring blood pressure and pulse rate in adult patient population.
The measuring method is an oscillometric blood pressure measurement with automatic sequence and refers to the auscultatory method as the reference standard.
The model version BPM 105 is equipped with a radio module to transmit the measurement data to a PC.
The device is not intended for neonatal use.

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)

(Division Sign-Off) 12/17/08
Division of Cardiovascular Devices

510(k) Number K081498