

OCT 31 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(k) number is: K072752.

1. Submitting Identification:

DataDancer Medical Systems
1644 Laurel Street
Chico, California 95928

Phone: 530-892-9086
FAX: 530-892-9086
Contact: Michael L. Kohut
Date Prepared: 24 October, 2008

2. Name of Device:

Trade Names: bp Limbo XL, bp Salsa XL & bp Tango XL
Common Name: Blood Pressure Log Software
Classification Name: Programmable Diagnostic Computer
Product Code: DQK

3. Predicate Devices:

Microlife Automated Blood Pressure Monitor
with personal computer software
Model: BP3AC1-1PC
510(k) Number: K060686

Panasonic Wrist Blood Pressure Monitor
Model: EW3037
510(k) Number: K042818

4. Device Descriptions:

4.1 **bp Limbo XL**

DataDancer Blood Pressure (*bp*) Log Software, Model "*bp Limbo XL*", is a Microsoft Excel software application designed to log one (1) daily set of blood pressure results obtained from a user's personal blood pressure monitor, for a period of one (1) year. The device provides users, who have a personal computer and Microsoft Excel software installed, a method of logging, organizing, plotting, printing and viewing their personal blood pressure performance.

The device is composed of twelve (12) monthly blood pressure (*bp*) Logs, a Meds Log, an Example Screen, a Help Screen, a Year Screen, a MD Letter and a Title or Welcome Screen. Instant Help is provided on most screens by moving the computer's screen pointer over designated items of interest. Each monthly *bp* Log is designed to print all logged results, graphs and supplementary data for easy physician review and insertion into a personal medical file. User Instructions are available on the Help Screen and can also be downloaded from the DataDancer web site in PDF format.

Users can enter the following information into monthly blood pressure (*bp*) Logs: Time of *bp* measurement, Body Weight, Systolic Pressure, Diastolic Pressure, Pulse Rate and Comments. Pulse Pressure, Mean Arterial Pressure, Body Mass Index, parameter averages and the Classification of Blood Pressure (*) are automatically calculated. A Year Screen is provided to view, compare and print the averaged results of all monthly *bp* Logs in tabular and graphical formats.

(*) Blood Pressure is classified according to the published document titled "*The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*"; NIH Publication Number 03-5233, May 2003.

4.2 bp Salsa XL

DataDancer Blood Pressure (*bp*) Log Software, Model "*bp Salsa XL*", is a Microsoft Excel software application designed to log blood pressure results obtained from a user's personal blood pressure monitor. The device provides users, who have a personal computer and Microsoft Excel software installed, a method of logging, organizing, plotting, printing and viewing their personal blood pressure performance within and across different blood pressure treatments.

The device is composed of ten (10) identical blood pressure (*bp*) treatment Logs, a Meds Log, an Example Screen, a Help Screen, a Summary Screen, a MD Letter and a Title or Welcome Screen. Instant Help is provided on most screens by moving the computer's screen pointer over designated items of interest. Each *bp* treatment Log is designed to print all logged results, graphs and supplementary data for easy physician review and insertion into a personal medical file. User Instructions are available on the Help Screen and can also be downloaded from the DataDancer web site in PDF format.

Users can enter the following within-treatment information into blood pressure (*bp*) treatment Logs: Date and Time of *bp* measurement, Body Weight, Systolic Pressure, Diastolic Pressure, Pulse Rate and Comments. Pulse Pressure, Mean Arterial Pressure, Body Mass Index, parameter averages and the Classification of Blood Pressure (*) are automatically calculated. A Summary Screen is provided to view and compare across treatment performance and print the averaged results of all treatment Logs in tabular and graphical formats.

(*) Blood Pressure is classified according to the published document titled "*The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*"; NIH Publication Number 03-5233, May 2003.

4.3 bp Tango XL

DataDancer Blood Pressure (*bp*) Log Software, Model "*bp Tango XL*", is a Microsoft Excel software application designed to log two (2) daily set of blood pressure results obtained from a user's personal

blood pressure monitor, for a period of one (1) year. The device provides users, who have a personal computer and Microsoft Excel software installed, a method of logging, organizing, plotting, printing and viewing their personal blood pressure performance.

The device is composed of twelve (12) monthly blood pressure (*bp*) Logs, a Meds Log, an Example Screen, a Help Screen, a Year Screen, a MD Letter and a Title or Welcome Screen. Instant Help is provided on most screens by moving the computer's screen pointer over designated items of interest. Each monthly Log is designed to print all logged results, graphs and supplementary data for easy physician review and insertion into a personal medical file. User Instructions are available on the Help Screen and can also be downloaded from the DataDancer web site in PDF format.

Users can enter the following information into monthly blood pressure (*bp*) Logs: Times of *bp* measurement, Body Weight, Systolic Pressure, Diastolic Pressure, Pulse Rate and Comments. Pulse Pressure, Mean Arterial Pressure, Body Mass Index, parameter averages and the Classification of Blood Pressure (*) are automatically calculated. A Year Screen is provided to view, compare and print the averaged results of all monthly *bp* Logs in tabular and graphical formats.

(*) Blood Pressure is classified according to the published document titled "*The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*"; NIH Publication Number 03-5233, May 2003.

5. Intended Use:

bp Limbo XL, *bp Salsa XL* and *bp Tango XL* are designed for Adult Blood Pressure Only or persons 18 years or older.

bp Limbo XL, *bp Salsa XL* and *bp Tango XL* are intended to be used as a personal blood pressure log to record patient measured results from a personal blood pressure monitor aiding in the management of hypertension as directed by a patient's physician or health care provider. The printed reports, and subsequent information contained within, are intended for review and interpretation by a physician and not as a stand alone diagnostic tool.

If *bp Limbo XL*, *bp Salsa XL* or *bp Tango XL* are used without a physician or health care provider relationship, all information must be considered educational, relating to the user's condition, and not as medical advice for the purpose of diagnosis, administration of treatment(s) or to prescribe medication(s).

6. Comparison to the 510(k) Cleared Devices (Predicate Devices)

6.1. Microlife Automated Blood Pressure Monitor (K060686)

The predicate device can input blood pressure results manually via computer keyboard or by a PC-link function which transfers blood pressure (*bp*) results measured on said predicate device hardware, via a USB cable, into a personal computer containing installed software that is part of the predicate device. The following comparison is limited to the software portion of the predicate device.

6.1.1. All Devices Incorporate the Following: (*bp Limbo XL*, *bp Salsa XL*, *bp Tango XL* and the *Microlife Predicate*)

- All devices are software based and require a personal computer.
- All devices use blood pressure (*bp*) results from a personal *bp* monitor.
- All devices display the following blood pressure measurement results: Systolic Pressure (SP), Diastolic Pressure (DP), Pulse Rate (PR), Pulse Pressure (PP), Mean Arterial Pressure (MAP), Date and Time of Measurement plus optional Comments.
- All devices plot line graphs of SP and DP.
- All display average results of SP, DP, PR, PP and MAP.
- All devices employ user identification.
- All devices print reports in color.
- All devices provide on-board user help.
- All devices use error detection algorithms.
- All devices can input *bp* results manually.

6.1.2. *bp Limbo XL*, *bp Salsa XL* and *bp Tango XL* Devices Differ as Follows from the *Microlife Predicate*:

- *bp Limbo XL*, *bp Salsa XL* and *bp Tango XL* devices Classify Blood Pressure.
- *bp Limbo XL*, *bp Salsa XL* and *bp Tango XL* devices calculate BMI (Body Mass Index) and plot Weight & BMI.

6.2. Panasonic Wrist Blood Pressure Monitor (K042818)

Unlike the Microlife Automated Blood Pressure Monitor, the Panasonic Wrist Blood Pressure Monitor does not have a USB link to any external device software program nor does it have any stand alone software. However, the device classifies blood pressure according to document titled "*The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*"; NIH Publication Number 03-5233, May 2003. Therefore, the predicate and all test devices classify blood pressure.

7. Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence:

bp Limbo XL, *bp Salsa XL* and *bp Tango XL* were developed in accordance with the General Principles of Software Validation: Final Guidance for Industry and FDA Staff.

The testing performed demonstrated the safety and effectiveness of the DataDancer Blood Pressure Log Software, Models *bp Limbo XL*, *bp Salsa XL* and *bp Tango XL*, by subjecting both the Microlife PC-link predicate and test devices to identical sets of blood pressure data. All devices produced substantially equivalent results as summarized below:

- | | |
|---|---------------------|
| ▪ Data sets held in memory: | Identical Results. |
| ▪ Calculated Averages for SP, DP, PR, PP and MAP: | Identical Results. |
| ▪ Pulse Pressure (PP): | Identical Results |
| ▪ Mean Arterial Pressure (MAP): | Identical Results |
| ▪ Graphical Plots for SP, DP and PR: | Comparable Results. |
| ▪ Parameter results displayed and in printed reports: | Identical Results. |

Using identical data sets, the Classification of Blood Pressure algorithm in the test devices produced results in agreement with the Panasonic predicate device.

8. Discussion of Clinical Test Performed:

Clinical testing was not required to demonstrate substantial equivalence of safety and effectiveness.

9. Conclusion:

We have demonstrated that the DataDancer Blood Pressure Log Software, Models *bp Limbo XL*, *bp Salsa XL* and *bp Tango XL*, are as safe and effective as the predicate devices, the Microlife Automated Blood Pressure Monitor's Personal Computer PC-link Software, Model BP3AC1-1PC and the Panasonic Wrist Blood Pressure Monitor's Classification of Blood Pressure algorithm, Model EW3037, based upon testing results using identical data sets.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

DataDancer Medical Systems
c/o Mr. Michael Kohut
President
1644 Laurel Street
Chico, California 95928

Re: K072752

Trade/Device Name: bp Limbo XL, bp Salsa XL & bp Tango XL
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DQK, DXN
Dated: October 17, 2008
Received: October 21, 2008

Dear Mr. Kohut:

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.

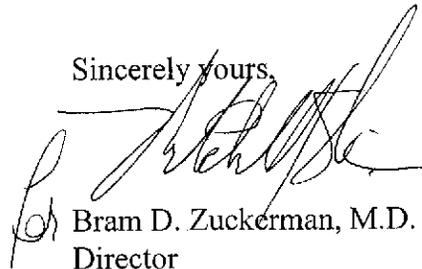
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with

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 Biometric's (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,



Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

 **DataDancer**
Medical Systems

530-592-9086
Phone & fax

1644 Laurel Street
Chico, California 95928 (USA)

mail@DataDancer.com

Indications for Use

510(k) Number (if known):	K072752
Device Names:	bp Limbo XL, bp Salsa XL & bp Tango XL

Indications for Use:

bp Limbo XL, bp Salsa XL and bp Tango XL are designed for Adult Blood Pressure Only or persons 18 years or older.

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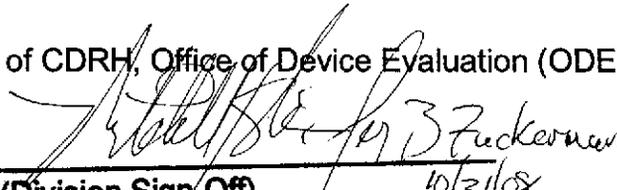
Prescription Use: NO
(Part 21 CFR 801 Subpart D)

(AND/OR)

Over-The-Counter Use: YES
(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) 10/31/08
Division of Cardiovascular Devices

510(k) Number K072752