

Premarket Notification 510(k)
Section 2 - Summary

CUFFABLE PLUS™

SEP 1 1999

510(k) SUMMARY
As required by Section 807.92 (e)

K990412

Company Name: Vital Signs, Inc
20 Campus Road
Totowa, New Jersey

Telephone Number: (973) 790-1330
EXT 356

Fax Number: (973) 790-4150

Official Contact: Anthony P. Martino
V.P. Quality Assurance and Regulatory Affairs

Date: August 12, 1999

Proprietary or Trade Name: CUFF-ABLE PLUS™

Common/Usual Name: Blood Pressure Cuff

Classification Name: Non-Automated Sphygmomanometers
(per CFR 870.1120)

Predicate Device: PyMaH Corp., Pregaged® Cuff with Antimicrobial
Treatment - K884421

Vital Signs, Inc., CUFF-ABLE® (Biomedical
Dynamics- K911213)

Device Description:

The device comprises a soft fabric with an integral bladder that is wrapped around a patient's limb and secured by a hook and loop closure. One or two tubes extend from the bladder and are connected to a non-invasive blood pressure measurement system. The blood pressure cuffs contain no latex. Sizes will include child through adult. The device is treated with an antimicrobial agent that helps prevent bacterial growth, mildew and odors. Each unit is packaged in a polyfilm bag.

20 Campus Road, Totowa, N.J. 07512 • 1 800 732-0760 • N.J. 201-790-1330 • Telex: 881786 (Vital Signs UD) • Fax: 201-790-3307



Premarket Notification 510(k)
Section 3 - Introduction and General Information

CUFF-ABLE PLUS

Introduction:

Vital Signs Inc., intends to market the CUFF-ABLE PLUS™ blood pressure cuff. The CUFF-ABLE PLUS™ blood pressure cuff is a disposable, single patient use device with an antimicrobial treatment used for indirect measurement of blood pressure. The CUFF-ABLE PLUS™ blood pressure cuff is of the same material and construction as the CUFF-ABLE®, single use blood pressure cuff currently manufactured by Vital Signs MN, Inc. and cleared under (Biomedical Dynamics) K911213 with the addition of an antimicrobial agent. The antimicrobial properties will inhibit the growth of bacteria and fungi.

Device Description:

The device comprises a soft fabric with an integral bladder that is wrapped around a patient's limb and secured by a hook and loop closure. One or two tubes extend from the bladder and are connected to a non-invasive blood pressure measurement system. The blood pressure cuffs contain no latex. Sizes will include child through adult. The device is treated with an antimicrobial agent that helps prevent bacterial growth, mildew and odors. Each unit is packaged in a polyfilm bag.

Intended Use:

The CUFF-ABLE PLUS™ blood pressure cuff is used in conjunction with non-invasive blood pressure monitoring systems by personnel properly trained in the use of manual and automatic sphygmomanometers. The device is non-sterile and is intended as a single patient use disposable device and is available in child and adult sizes.

Cautions:

Federal Law restricts this device to sale or on order of physician.
If irritation should occur, discontinue use.

Summary of Functional and Environmental Testing:

The CUFF-ABLE PLUS™ blood pressure cuff was compared to the CUFF-ABLE®, single use blood pressure cuff to confirm that its functional and physical performance characteristics were equivalent. The ANSI/AAMI SP-9, 1994 Standard was used in part to select the key performance attributes to measure. The cuffs were equivalent in performance in regards to Cuff Closure, Pressure Capacity and Repeated Inflations. Testing included, but was not limited to hook, fabric and flange seal strengths, seal burst



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

~~SEP 1 1999~~

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Anthony Martino
Vice President Quality Assurance
and Regulatory Affairs
Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512

Re: K990412
CUFF-ABLE PLUS™
Regulatory Class: II (Two)
Product Code: 74 DXQ
Dated: June 9, 1999
Received: June 10, 1999

Dear Mr. Martino:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

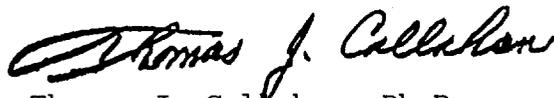
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Anthony Martino

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

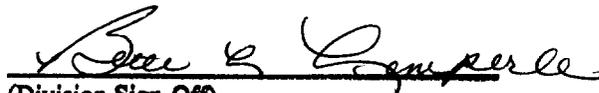
INDICATION FOR USE
STATEMENT

510(k) Number: K990412

Device Name: CUFF-ABLE PLUS™

Indications for Use:

The CUFF-ABLE PLUS™ blood pressure cuff is used in conjunction with non-invasive blood pressure monitoring systems by personnel properly trained in the use of manual and automatic sphygmomanometers. The device is non-sterile and is intended as a single patient use disposable device and is available in child and adult sizes.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K990412

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-the-counter use
(Per CFR 801.109)