FEB 2 5 2000

K994044

510(k) SUMMARY

Submitter's Name:	Vital Signs, Inc 20 Campus Road Totowa, New Jersey
Official Contact:	Anthony P. Martino VP Quality Assurance and Regulatory Affairs
Telephone Number:	(973) 790-1330 ext. 356
Fax Number:	(973) 790-4150
Date:	November 24, 1999
Proprietary or Trade Name:	CLEEN-ABLE™
Common/Usual Name:	Blood Pressure Cuff
Classification Name:	Cuff, Blood Pressure (Per CFR 870.1120)
Predicate Device:	CRITIKON's DURA-CUF®

Device Description:

The device is comprised of one or two tubes attached to a soft fabric with an integral inflatable bladder that is wrapped around a patient's limb and secured by a hook and loop closure. The tubing connects to a non-invasive blood pressure measurement system. The blood pressure cuffs contain no latex. Sizes will include infant through adult. Each unit is packaged in a polyfilm bag. Connectors, adapters and pump bulb /valve assemblies are available for use with a variety of manual and automatic sphygmomanometers.

Intended Use:

The CLEEN-ABLE™ 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 multi- patient reusable device and is available in infant through adult sizes.

Technology Comparison to Predicate Device:

Item	CLEEN-ABLE™	DURA-CUF®
Intended Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Prescription Device	Yes	Yes
Intended Population	Infant - Adult	Infant - Adult
Labeling	Multi- patient use	Multi -patient use
Materials	Nylon fabric/PVC	Nylon fabric/PVC or polyurethane
Number of tubes	1 and 2	1 and 2
Cleaning Instructions	Provided, same as DURA-CUF®	Provided

Summary of Non-Clinical Performance Testing:

Bench testing was conducted to demonstrate performance (safety and effectiveness) of the CLEEN-ABLE™ blood pressure cuff. The key performance requirements and the test methodologies were selected from the ANSI/AAMI SP-9, 1994 Standard for Cuffs with Integral bladder. This standard is referred to in the FDA Guidance for Industry document titled "Non–Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1. The cuff performance testing included but was not limited to Cuff Closure/construction, Pressure Capacity and Repeated Inflation testing, and systems leak testing.

Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Section 807, and based on the information provided in this premarket notification, Vital Signs, Inc. concludes that the CLEEN-ABLE™ Blood Pressure Cuff is safe, effective and substantially equivalent to the predicate device as described herein and meets the appropriate requirements of ANSI/AAMI SP-9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Mr. Anthony P. Martino
VP of Quality Assurance and Regulatory Affairs
Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512

Re: K994044
Cleen-Able™ Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: DXQ
Dated: November 24, 1999
Received: November 29, 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.

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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE
STATEMENT

510(k) Number: K994044

Device Name: CLEEN-ABLE™

Indications for Use:
The CLEEN-ABLE™ 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 multi-use device and is available in infant through adult sizes.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K994044

Concurrence of CDRH, Office of Device Evaluation (ODE)