JUL 9 2002 K013434

510(k) Summary
for
VP-2000/1000

1. Sponsor

Colin Corporation
2007-1 Hayashi Komaki, 485 Japan

Contact Person: Mark Rison, Sr. Director, QA/RA
Colin Medical Instruments Corporation
5850 Farinon Dr. San Antonio, TX. 78249

Telephone: 210-690-6200

Date Prepared: October 13, 2001

2. Device Name

Proprietary Name: VP-2000/1000
Common/Usual Name: Non-invasive blood pressure measurement and vascular profiling system
Classification Name:
The following devices classifications apply to this device.

Names	Class	CFR
Non-invasive blood pressure monitor	II	870.1130
Phonocardiograph	I	870.2390
Heart sound transducer	II	870.2860
Heart rate monitor	II	870.2300

All of these devices were reviewed by the Cardiovascular Devices Panel.

3. Predicate Devices

Press-Mate BP8800 (510k # K 921048)
Press-Mate Advantage (510k # K973637)
IMEXLAB 9100 (510k # K973562)
PILOT 9200 (510k # K922668)
CADIscope (510k # K990809)

4. Device Description

The BP-203 RPE II Series VP-1000 and VP-2000 monitor is a prescriptive device intended for use only by health care professionals. The monitors are designed to assist in the detection of peripheral vascular diseases and have been designed and tested to automate published clinical diagnostic test methods. The device is capable of measuring non-invasive blood pressure (NIBP), ECG (lead I), non-invasive pulse waveforms, and heart sounds. In addition, the monitors are also capable of calculating specific clinically recognized indices such as ABI (Ankle-Brachial Index) and PWV (Pulse Wave Velocity).

5. Intended Use

VP-2000/1000 is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases. It has a capability of measuring; non-invasive blood pressures, heart rate, pulse wave, and heart sound.

It also has a capability of calculating ABI (Ankle Brachial Index), Pulse Wave Velocity and Augmentation Index.

The instrument is used in a vascular laboratory, clinic, hospital, doctor's office, and other medical facilities where the non-invasive peripheral vascular test is conducted.

It is used an adult patients only.

6. Technological Characteristics and Substantial Equivalence

VP-2000/1000 is substantial equivalent to the legally marketed devices listed in the body of this document.

7. Performance Testing

Biocompatibility test, Environmental Tests including Electrical safety tests, EMC tests and Clinical tests were performed and confirmed the performance of VP-2000/1000 met the product requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2002

Colin Instrument Corp.
c/o Mr. Mark Rison
Sr. Director, Regulatory Affairs / Quality Assurance
5850 Farinon Drive
University Technology Park
San Antonio, TX 78249

Re: K013434
Device Name: Models VP-1000 and VP-2000
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II
Product Code: DXN
Dated: April 15, 2002
Received: April 16, 2002

Dear Mr. Rison:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number 013434

Device Name: VP-2000/1000

Indications For Use:
VP-2000/1000 is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases. It has a capability of measuring; non-invasive blood pressures, heart rate, pulse wave, and heart sound

It also has a capability of calculating ABI (Ankle Brachial Index), Pulse Wave Velocity, and Augmentation Index.

The instrument is used in a vascular laboratory, clinic, hospital, doctor's office, and other medical facilities where the non-invasive peripheral vascular test is conducted.

It is used on adult patients only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K013434

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)