SEP 2 5 1998

K973637

510(K) Summary for The PressMate Advantage

1. Date this summary was prepared:
September 15, 1997

2. Submitter's Name and Address:

Colin Medical Instruments Corporation
5850 Farinon Drive
San Antonio, Texas 78249

3. Contact Person:

Mr. Mark Rison
Senior Director, RA/QA
Telephone: 1-800-829-8100
Telefax: 1-210-696-8808

4. Device Name

Trade/ Proprietary Name:
PressMate Advantage

Common Name:
Automated Non-Invasive Blood Pressure Monitor / Vital Signs Monitor with / without optional ECG / RR and Sp02

Classification Names:
Non- Invasive Blood Pressure Measurement System

5. Predicate Devices

The legally marketed devices to which equivalence is being claimed are:

PressMate Model 8800 Non-Invasive Blood Pressure Monitor K# (K951048)
Manufactured by Colin Medical Instruments Corporation

Escort Model 102 K# (K872291) Portable Vital Signs Monitor
Manufactured by: Medical Data Electronics Incorporated

6. Device Description

The PressMate Advantage Monitor measures, displays and (optionally) prints the following parameters:

1. NIBP (systolic, Diastolic, Mean and Pulse Rate)

2. ECG

3. Body Temperature

4. Sp02 (Oxygen Saturation and Pulse Rate)

7. Intended Use:

The PressMate Advantage monitors non-invasive blood pressure (NIBP), oxygen saturation (Sp02), ECG, Respiration Rate and Body Temperature of an adult, pediatric, or neonate in a clinical setting.

8. Comparison of Technological Characteristics:

The PressMate Advantage uses the standard oscillometric technique for obtaining NIBP. Nellcor Sp02 technology for Oxygen saturation, standard ECG technology and YSI temperature probes.

9. Nonclinical Tests Used in Determination of Substantial Equivalence:

The design of the PressMate Advantage has been thoroughly validated at the unit and system level. Non-clinical tests were conducted to determine the complete system and has been tested to the electrical safety requirements and the Electromagnetic Compatibility requirements of EN 60601.

10. Conclusions From Nonclinical Testing:

The testing of the PressMate Advantage demonstrates that the performance is substantially equivalent to predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

Mr. Howard K. Mann
Sr. Director QA/RA
Colin Medical Instruments Corp.
5850 Farinon Drive
University Technology Park
San Antonio, TX 78249

Re: K973637
Press-Mate Advantage
Regulatory Class: II (Two)
Product Code: DXN
Dated: June 30, 1998
Received: July 2, 1998

Dear Mr. Mann:

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"(21 CFR 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

Intended Use

Device Name: PressMate Advantage

Indications For Use:

The PressMate Advantage monitors non-invasive blood pressure (NIBP), Oxygen saturation (Sp02), ECG, Respiration Rate and Body Temperature of an Adult, Pediatric or Neonate in the clinical setting.

(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, Respiratory,
and Neurological Devices
510(k) Number K973637

Prescription Use ✓ OR Over-the Counter Use
(Per 21 CFR 801.109)