



MAY - 9 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Randy Kellogg
Vice President Marketing and Medical Sales
Omron Healthcare, Incorporated
1200 Lakeside Drive
Bannockburn, Illinois 60015

Re: K063690

Trade/Device Name: Colin Press Mate, Model BP S510

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia, Detector and Alarm (including ST-Segment Measurement and Alarm)

Regulatory Class: II

Product Code: MHX, DSK, DPS, DXN, DQA and CCK

Dated: April 12, 2007

Received: April 13, 2007

Dear Mr. Kellogg:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K063690

Device Name: Colin Press Mate, Model BP S510

Indications for Use:

The Colin Press Mate, Model BP S510 is intended to be used to monitor electrocardiography (ECG), heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressures) (NIBP), functional arterial oxygen saturation (SpO₂), pulse rate (PR), respiration (RR), body temperature (Temp), invasive blood pressure (IBP) and capnography (EtCO₂ and InCO₂).

The intended patient populations are: adults and pediatrics of at least 14 years of age and weighing more than 35 kg and infants can only be monitored with the oscillometric cuff.

Environment of use: All areas of a hospital and hospital type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist.

Note: Hospital use typically includes such areas as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub acute care centers.

Prescription Use **XX** or Over-the-counter use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chen

(Signature)
Department of Anesthesiology, General Hospital,
Quality Control, Dental Devices
510(k) Number: K063690