DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1999

A&D Engineering, Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K982481
A&D Medical UA-767PC Digital Blood Pressure Monitor
Regulatory Class: II (Two)
Product Code: DXN
Dated: September 11, 1998
Received: September 14, 1998

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of September 25, 1998 and our corrected substantially equivalent letter of September 30, 1998, regarding the indications for use statement.

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

510(k) Number (if known): K982481

Device Name: UA-767PC Digital Blood Pressure Monitor

Indications for Use:

The UA-767PC is designed to be used by end users who are eighteen (18) years and older at home and doctor/nurse office to monitor their blood pressure (systolic and diastolic) and pulse rate. At the end of each measurement, the results will be stored in the UA-767PC memory. UA-767PC through its communication port can also transfer the measurements stored in memory to other electronic devices, such as a PC, a modem, or a printer. The end user should not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation. UA-767PC uses the oscillometric method to conduct the measurement. It is not designed for ambulatory use. The arm circumference range shall be between 5.1 inches (13.0 cm) to 17.7 inches (45.0 cm).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982481

Prescription Use _____ or Over-The-Counter Use ✓

(Optional Format 1-2-96)