DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 8 2002

Eikon Healthcare Device Corp.
c/o Dr. Jen, Ke-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-CHU City
Taiwan, ROC

Re: K021239
Trade Name: Eikon Automatic Digital Blood Pressure Monitor, Model HD-400M
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 5, 2002
Received: August 12, 2002

Dear Dr. Ke-Min:

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 (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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EIKON Healthcare Device Corp.
TOMSON IND. Park, 5F-4, No. 14, Lane 609, Sec. 5, Chung-Shing Road,
San-Chung City, Taipei Hsien, 241, Taiwan, ROC
Telephone: 886-2-29995373 Fax: 886-2-29995483
Email: honbin@ms27.hinet.net

Applicant: ***EIKON Healthcare Device Corp.***

510(k) Number (if known): TBA K021239

Device Name: EIKON AUTOMATIC DIGITAL BLOOD PRESSURE MONITOR HD-400M

- *Indications for use:*

The EIKON automatic digital blood pressure monitor, Model HD-400M, is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 16, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.3" – 8.5".

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

Concurrence of CDRH, office of Device Evaluation (ODE)

510(k) Number K021239

Prescription Use _____ OR Over – The – Counter – Use X

(Per 21 CFR 801.109) (Optional Format 1-2-96)