DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDCON LTD.
c/o Dr. Eli M. Orbach
Internationaj Regulatory Consultants
POB 6718, Erfrat 90435
ISRAEL

Re: K971181
MDVIEW (PACS) Medical Image Communication
and Storage Device (Cardiac Device Accessory)
Dated: July 14, 1997
Received: July 16, 1997
Regulatory Class: II
21 CFR 892.1600/Procode: 90 IZI

JUL 29 1997

Dear Dr. Orbach:

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 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 requirement, 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) 594-4613. 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/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 9 1997

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

K971181

Submitter: Medcon Ltd. Kiryat Atidim, P.O. Box 518164 Tel Aviv 61581Israel Tel: +972.3 6487702, Fax: +972. 3 6482310

Name of the Device: The MDVIEW-MEDCON's DICOM Viewer

Predicate Devices: The MDVIEW is substantially equivalent to The CRS 2000 subsystem of the Kodak Science Digital Image System. ...

Description of the Device: The MDVIEW is a software device intended to retrieve, display, print and save cardiac catheterization laboratory image studies from CD-R media, and to view these images on a PC computer in real time mode. Digital imaging from the cardiac catheterization laboratory is recorded on the CD-R in conformance with the DICOM standard. These loss free images provide physicians with a valuable tool for diagnostic review and analysis. The differences between the MDVIEW and the predicate device raise no new issues of safety or effectiveness.

24 March,1997

Date

Mr.Uzi Blumensohn, General Manager

510(k) Number (if known): K971181

Device Name: The MDVIEW - MEDCON'S DICOM VIEWER

Indications For Use:

The MDVIEW is a software device intended to retrieve, display, print and save cardiac catheterization laboratory image studies from CD-R media, and to view these images on a PC in real-time mode.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

for LLY

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971181