DEC 29 1999

K993338

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitter: *IBM Israel Ltd.*, 2 Weizmann Street Tel Aviv ISRAEL 61336
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Name of the Device: IBM Integrated Digital Medical Record (IDMR).

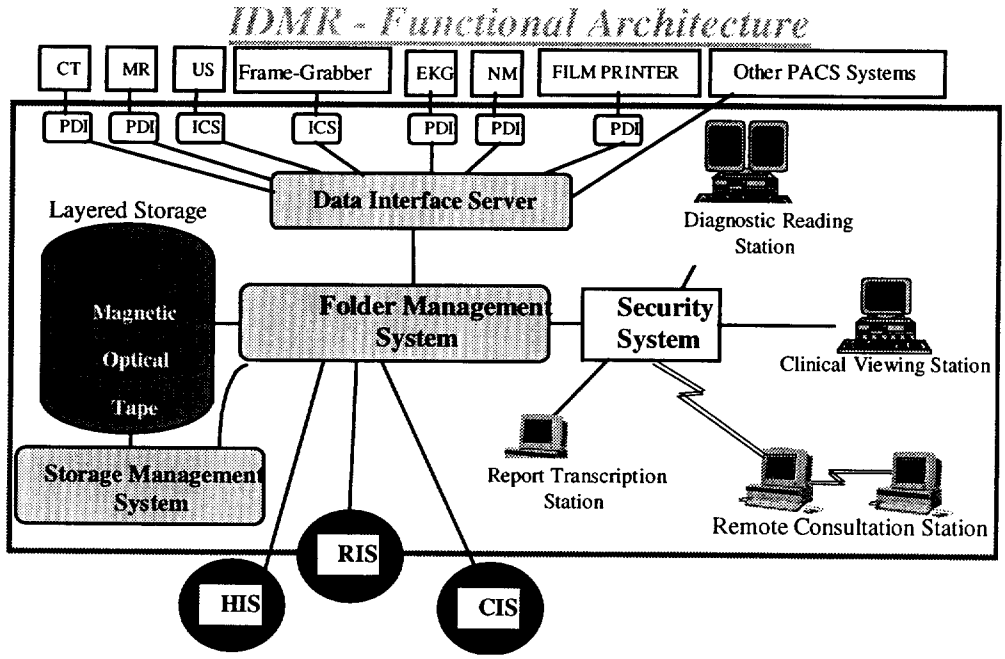
Predicate Device The IDMR is substantially equivalent to the IMAGING WORKBENCH, manufactured by BRIT SYSTEMS, subject of K943383.

Intended Use: The IBM Integrated Digital Medical Record (IDMR) provides integrated access to digital patient folders and manages digital information flow in a networked health care environment. It integrates all sources of multimedia patient data into a single patient folder, combining demographic, clinical, and radiological information.

Description of the Device:

- The IDMR system is UNIX and Windows/NT based, with UNIX (IBM RS/6000 and AIX) servers and clients, and Windows/NT clients.
- IDMR uses standard IBM hardware and software (RISC System/6000, AIX, IBM/PC, ADSM) components.
- IDMR uses the industry standard structured query language (SQL) database. The system currently supports IBM DB2/6000 and Oracle databases.
- IDMR is designed to operate over local and wide area networks. Standard transmission control protocol/Internet protocol (TCP/IP) is used throughout the communication networks. The communication systems supported include (but are not limited to) token ring, Ethernet, fiber distributed data interface (FDDI), asynchronous transfer mode (ATM), and integrated services and digital network (ISDN).
- IDMR is implemented using the C and C++ programming languages.
- The system implements state-of-the-art client/server technology and enables seamless addition of hardware modules. The system servers (file management system (FMS), data interface server (DIS), storage management system (SMS) can be installed on larger central UNIX machines or can be distributed to smaller machines in various departments.
- IDMR supports DICOM 3.0 standard for data model, and interconnectivity protocol.

The system architecture is shown in the following figure:



Dr. Uri Shani, Manager of IDMR Development, September 30, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1999

IBM Israel Ltd.
C/o Eli Orbach
International Regulatory Consultants
P.O. Box 6718
Efrat 90435 ISRAEL

Re: K993338
Integrated Digital Medical Record
Dated: September 30, 1999
Received: October 5, 1999
Regulatory Class: II
21 CFR 892.2050/procode: 90 LLZ

Dear Mr. 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 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K993338.

Device Name. : Integrated Digital Medical Record (IDMR).

Indications For Use: The IBM Integrated Digital Medical Record (IDMR) provides integrated access to digital patient folders and manages digital information flow in a networked health care environment. It integrates all sources of multimedia patient data into a single patient folder, combining demographic, clinical, and radiological information.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993338

Prescription Use X OR Over The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)