FEB 10 2000

510(k) SUMMARY

DBA Systems, Inc.'s ImagClear® System

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Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: July 23, 1999

Name of Device and Name/Address of Sponsor

ImagClear® Mammography Review System
DBA Systems, Inc.
1200 South Woody Burke Road
Melbourne, Florida 32902-0550

Common or Usual Name

ImagClear® System

Classification Name

Picture Archiving and Communication System

Predicate Devices

DBA's previously cleared ImagClear® Film Digitizer (K932760) and MedImage, Inc.'s Galen™ Software (K946334)

Intended Use

The ImagClear® System is intended to digitize analog medical images, which will be viewed, archived, or electronically shared with other health care professionals. The ImagClear® System is specifically indicated for the digitization of mammographic images for review and analysis, but not as the sole basis for screening or diagnosis.

Technological Characteristics and Substantial Equivalence

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Essentially, the ImagClear® System is composed of two previously cleared devices: (1) the ImagClear® Film Digitizer, which DBA obtained FDA 510(k) clearance for use as a medical film digitizer with a mammography indication; and (2) a modified version of the previously Galen™ Software. The interfacing of these two previously cleared devices raise no new questions of safety or effectiveness because it does not alter the intended use of either device.

The first component of the ImagClear® System, the ImagClear® Film Digitizer, is a CCD-based digitizer which provides 16 bits of grayscale resolution. It produces at minimum a 4K x 5K image matrix, which is adequate for high quality mammography films. The second component of the ImagClear® System, the modified Galen™ Software, organizes the digitized mammography images into studies and sessions. The digitized mammogram studies and sessions may be viewed by using an overall or bilateral display (*i.e.,* display provides comparisons between left and right breasts or old and new images). The software also allows physicians or technicians to create on-line mammography reports. In addition, the digitized mammogram studies and sessions and on-line reports may be viewed, archived on a central file server, or electronically shared with other health care professionals.

The ImagClear® System and its predicates, the ImagClear® Film Digitizer, and the Galen™ Software, have essentially the same technological characteristics. As described above, the ImagClear® System is basically the interfacing of the ImagClear® Film Digitizer with a modified version of the previously cleared Galen™ Software. No changes have been made to the previously cleared ImagClear® Film Digitizer in the combination of these two devices. Thus, the ImagClear® Film Digitizer's technological characteristics have been, for all intents and purposes, incorporated into the ImagClear® System. The principal technological distinction between the ImagClear® System's software and the previously cleared Galen™ Software is that the cleared Galen™ Software did not have all the technological specifications to accommodate a mammography indication. Accordingly, DBA and MedImage collaboratively made modifications to the cleared Galen™ Software so that the modified software could accommodate the digitized mammography images which are generated by the ImagClear® Film Digitizer.

If one reviews these software modifications, it is clear that the changes do not raise any new questions of safety or efficacy. Rather, the modifications are essentially formatting and other changes to allow the most effective presentation of the same kinds of images already included in the digitizing capabilities of the cleared film digitizer. Moreover, internal storage, archiving, and transfer capabilities of the cleared Galen™ Software have been enhanced to accommodate the mammography images.

In summary, while there are some differences between the ImagClear® System and its predicate device, the previously cleared Galen™ Software, these differences are minor and raise no new questions of safety and efficacy.

Performance Data

None required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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DBA Systems, Inc.
C/O Jonathan S. Kahan, J.D.
Partner, Hogan & Harston, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K992467
ImagClear® Mammography Review System
Dated: November 12, 1999
Received: November 12, 1999
Regulatory class: II
21 CFR 892.2030/Procode: 90 LMA

Dear Mr. Kahan:

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): K992467

Device Name: ImagClear® Mammography Review System

Indications for Use:

The ImagClear® Mammography Review System is intended to digitize analog medical images, which will be viewed, archived, or electronically shared with other health care professionals. The ImagClear® System is specifically indicated for the digitization of mammographic images for review and analysis, but not as the sole basis for screening or diagnosis.

(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 K992467

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)