JUN 2 0 2003

K031248



# E 510(k) Summary

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| **Submitter's Name:** | MiraMedica, Inc. |
| **Submitter's Address:** | 15466 Los Gatos Blvd., Suite 109 PMB #171, Los Gatos, CA, 95032 |
| **Submitter's Telephone:** | (408) 858-0718 |
| **Contact Name:** | Wido Menhardt |
| **Date Summary was Prepared:** | April 11, 2003 |
| **Trade or Proprietary Name:** | Consultiva™ Report Station (RS) |
| **Common or Usual Name:** | System, Image Processing, Radiological |
| **Classification Name:** | Picture archiving and communications system (21 CFR 892. 2050) |

**Predicate Devices:**

| Device Name | 510(k) Number |
|---|---|
| Coronis 3MP Medical Flat Panel Display System | K013922 |
| IMPAX Workstations | K022292 |
| ImageChecker CT Workstation | K023003 |

**Description of the Device and Summary of the Technological Characteristics:**

The Consultiva™ Report Station (RS) is a Windows-based program that gathers digitized medical images from a specified location on hard disk, and displays those images on a monitor, with Computer Aided Detection (CAD) results (or other annotations) overlaid on top of the images. The RS provides a User Interface (UI) that allows the user to initiate the display of the images . The RS also provides the capability to print a CAD report.

The primary data sources for this system include the low resolution digital images and the CAD results. The visualization of CAD and images requires no explicit requirements for user manipulation of the data (zoom, pan, window level, etc). The visualization features of the RS include:

- The ability to display medical images at a reduced resolution and fixed size.
- The ability to enlarge an image.
- The ability to display the CAD results as an overlay over the displayed digitized images.

**Indications for Use:**

The Consultiva™ Report Station is a software application intended to be used to display low resolution, non-diagnostic medical images with annotations such as regions-of-interest or CAD marks.

**Substantial Equivalence:**

The RS is similar to predicate devices such as the R2 Technology ImageChecker CT Workstation, Agfa IMPAX Diagnostic Display Station, and BARCO Coronis 3MP Medical Flat Panel Display System.

**Testing:**

Various tests of the software will be done to verify system specifications are being performed. Verification procedures with pass/fail criteria were developed to ensure that the product met all the specified requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Wido Menhardt, Ph.D.
General Manager and
Chief Technical Officer
Miramedica, Inc.
15466 Los Gatos Blvd.
Suite 109, PMB#171
LOS GATOS CA 95032

Re: K031248
Trade/Device Name: Consultiva™ Report Station Model RS-1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 15, 2003
Received: April 29, 2003

Dear Dr. Menhardt:

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 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 one of the following numbers, based on the regulation number at the top of the letter:

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| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# D Indications for Use Statement

Ver/ 3 – 4.24.96

Applicant: MiraMedica, Inc.

510(k) Number (if known): K-3 1248

Device Name: Consultiva™ Report Station

Indications For Use:

The Consultiva™ Report Station is a software application intended to be used to display low resolution, non-diagnostic medical images with annotations such as regions-of-interest or CAD marks.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K 031248

Prescription Use √
per 21 CFR 801.109

Over the Counter Use _____