

OCT 21 1998

510(k) Summary

K982862

RADWORKS MEDICAL IMAGING SOFTWARE WITH QUALITY CONTROL MODULE

Common/Classification Name: Digital Image Communications System

Appicare Medical Imaging, B.V.
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Contact: Bernie van Welt
Prepared: July 6, 1998

A. LEGALLY MARKETED PREDICATE DEVICES

The **RadWorks Medical Imaging Software with Quality Control Module** is substantially equivalent to the original version of the **RadWorks Medical Imaging Software (K962699)**.

B. DEVICE DESCRIPTION

The **RadWorks Quality Control Module** is intended to be used by authorized staff to perform various quality control operations on **RadWorks** imaging studies before they are made available to other locations on the network. These operations include confirming or editing patient characteristics, reviewing the status history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.

C. INTENDED USE

The **RadWorks Quality Control Module** is intended to be used by authorized staff to perform various quality control operations on **RadWorks** imaging studies before they are made available to other locations on the network. These operations include confirming or editing patient characteristics, reviewing the status history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.

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D. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the modified device are identical to those of the original device.

E. TESTING

Software testing of the new module followed Applicare's normal procedures. During the design phase, a software test plan is developed, containing a detailed description of relevant test procedures. Each test procedure is documented and contains a description of what to test, what the expected results are, when to test, by whom the tests will be performed, which resources (such as automated test tools) will be used and how the test results are recorded.

F. CONCLUSIONS

In summary, Applicare has demonstrated that the intended use for **RadWorks Medical Imaging Software with Quality Control Module** is the same as that of the original (predicate) device, and the technological characteristics have been described in sufficient detail to demonstrate that they are the same as those of the predicate device. Therefore, this premarket notification has demonstrated Substantial Equivalence as defined and understood in the Food, Drug, & Cosmetic Act and its amendments.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Appicare Medical Imaging, B.V.
c/o T. Whit Athey, Ph.D.
C.L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852

Re: K982862
RadWorks Medical Imaging Software with
Quality Control Module
Dated: August 13, 1998
Received: August 13, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Athey:

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 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) 594-4643. 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,

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K982862

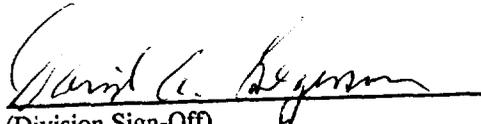
Device Name: RadWorks Medical Imaging Software with Quality Control Module

Indications For Use:

The **RadWorks Medical Imaging Software**, from Applicare Medical Imaging, B.V., when installed on an appropriate hardware platform, is intended to provide capability for the acceptance, display, storage, and digital processing of medical images. Options allow for additional capability, including transmission of images over local area networks or public communications channels, digitization of film images, acceptance of digital images directly from different medical image modalities, and quality control review and revision of studies.

(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 K982862

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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