ARRI®

K993283

Summary of Safety and Effectiveness Information For 510(k) Submission Medical Image Digitizer

General Information:

Proprietary Name:	*OSCAR NET/CD*
Common Name:	Picture archiving and communications system
Classification Name:	*Picture archiving and communications system,§ 892.2050*
Classification:	*Class II*
Classificatin Number:	
Intendet use:	*The device is intendet to be used to convert an medical film/S-VHS Tape -Image into a digital format(DICOM),electronic storage for an medical image and electronic tranfer of medical image data.*
Legally marketed device:	*MEDIMAGE*
Proprietary Name:	*MEDIMAGE and Cardio Viewing Station*
Common Name:	
Classification Name:	
Classification:	*Class II*
Classificatin Number:	
Date of Submission:	*Nov.19.1997*
510(k) Number:	*K 912275*

Standards for OSCAR NET/CD:

1. **DIN 6856,Part1**
   Demands for the manufacture and the operation
   Of viewing apparatus for the evaluation of
   tansparent images in medical diagnostics.
2. **DIN 6856,Part2**
   Quality-guaranteeing meaures in medical
   Diagnostics,
   -testing procedures,measuring instruments
3. **EN 60601-1**
   -IEC 601-1
   -VDE 0750 T1
4. **EN 50082-1**
   -VDE 839 T82-1
5. **EN 60601-1-1**
   -IEC 601-1-1
   -VDE 0750 T1-1
6. **EN 60601-1-2**
   -IEC 601-1-2
   -VDE 0750 T1-2
7. **EN 60601-1-4**
   -IEC 601-1-4
   -VDE 0750 T1-4
8. **EN 55022**
   -VDE 878 T22/A1
   -CISPR 22

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25.6.1999/ks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2000

i.V. Thomas Popp
Product Group Manager
Arnold & Richter Cine Technik GMBH & Co.
Turkenstrasse 89
Munich 80799, By
GERMANY

Re: K993283
ARRI-Oscar Net/CD (Image Work Station)
Dated: September 29, 1999
Received: September 30, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Popp:

This letter corrects our substantially equivalent letter of December 29, 1999, regarding the 510(k) number being incorrect. We apologize for the error and hope it has not caused any inconvenience.

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for CAPT Daniel 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): K993283

Device Name: PICTURE ARCHIVING AND COMMUNICATION SYSTEM

Indications For Use:

The Pacs Unit ARRI OSCAR NET/CD will be used to acquire, display, process, archive, retrieve, and transmit diagnostic medical images and information about these images in a single user or network enviroment. The typical users are trained medical professionals.

(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 K993283

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

(Optional Format 1-2