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ARNOLD & RICHTER CINE TECHNIK GMBH & CO. BETRIEBS KG

TÜRKENSTRASSE 89 · D-80799 MÜNCHEN

ARNOLD & RICHTER CINE TECHNIK · POSTFACH 400149 · D-80701 MÜNCHEN

Summary of Safety and Effectiveness Information for 510 [k] Submission Radiographic film illuminator

General Information:

Proprietary name:	Arripro 35 St / TV
Common name:	---
Classification Name:	Radiographic film illuminator
Classification:	Class II
Classification Number:	
Intended use:	The device is intended to be used for the projection, diagnosis and quantitative evaluation of 35 mm cineradiographic images
Legally marketed device:	CAP 35BIII / CINE 275
Proprietary Name:	Cineangiogram projector
Common Name:	--
Classification Name:	Class II
Classification:	--
Classification Number:	K 971128
Date of submission:	--

DIN-Standards applied for the Arripro 35 St /TV

1. **DIN 6856, Part 1**
   Demands for the manufacture and the operation of viewing apparatus for the evaluation of transparent images in medical diagnostics.
2. **DIN 6856, Part 2**
   Quality-guaranteeing measures in medical diagnostics,
   - testing procedures, measuring instruments
3. **DIN 19045, Part 8**
   Projection of still pictures and motion pictures for educational and home use.
4. EN 55011
   - CISPR 11
   - DIN NDE 0875-T11
   - VDE 0875-T11
5. EN 50082-2
   - DIN EN 50082-2
6. EN 60950
   - IEC 950
   - DIN EN 60950
   - VDE 0805
7. EN-61010-1
8. EN-60555-2
9. EN 60555-3

ARRI

Technological Characteristics and the intended use of the device

The ARRIPRO 35 was designed to fulfil the special requirements in view of an increasing demand for image quality and evaluation precision of 35 mm cardangiofilm material which could only be met with the innovative development of a practice-oriented projector. This projector which was developed using state-of-the-art technology for ease of operation, has an outstanding image quality for the projection, diagnosis and quantitative evaluation of 35 mm cine radiographic images.

The ARRIPRO 35 St / TV has the following functions:

Rapid Film Transport and Simple Operation
Film transport via a patented intermittent film drive system enables a film transport interval of less than 0.01 sec. regardless of projection speed. Constant film tension and reliable film transport is guaranteed through the use of a computer-controlled drive system for the film platter motors.
Film loading is both fast and simple as a result of the computer-controlled system.

Optimized Image Quality with Flicker Free Projection
Image brightness, frame steadiness and image clarity have been optimized for all applications.

High Speed Shuttle
High speed winding and quick localization of specific film frames is accomplished by using the projector's high speed shuttle mode.

Revolving Lamp Holder
The ARRIPRO 35 is equipped with a revolving lamp holder containing three (3) lamps, two (2) 300 W halogen lamps and one (1) 400 W HTI-lamp for bright wall projection.

Optimum Wall Projection
The ARRIPRO 35 also functions as an excellent quality wall projection unit.

Computer and Video Connections
A video output enables the connection of additional monitors, video recorder and video printer.

B&W-CCD-TV Camera
B&W-CCD-TV camera with motor-driven x-y zoom carriage as well as motor driven focusing. TV-image can be panned in all directions and zoomed up to 3.0 times.

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8. EN 60555-3
9. EN 50082-2
   - DIN EN 50082-2
   - VDE 839-T82-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arnold & Richter Cine Technik
GmbH & Co. Betriebs KG
c/o Carole Stamp
TUV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K973115
Arripro 35 St / TV (35 mm film viewer)
Dated: August 18, 1997
Received: August 20, 1997
Regulatory Class: I
21 CFR 892.1890/Procode: 90 LXC

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Dear Ms. Stamp:

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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

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

510(k) Number (if known):_____

Device Name: Radiographic Film Illuminator

Indications For Use:

The device is used for the diagnosis and quantitative evaluation of 35 mm cine radiographic images, which originating from radiographic imaging like Angiography.
The device contains a visible light source covered with a translucent front that is intended to be used to view medical cine radiographic images (CFR 21 part 892.1890). It also allows to be used for wall projection. The medical device is not part of a diagnostic x-ray system.

The device may only be operated in cathlabs, lecture halls and doctors' consulting rooms. The device is only for use by 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 K973115

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2

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