Section 9 - SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary

Ferrania, March 30, 2001

Ferrania S.p.A.
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Device:

Trade name:	LifeRay™ WL Cassette LifeRay™ KW Cassette
Common Name:	Radiographic film cassette
Classification Name:	Radiographic film cassette (per 21 CFR 892.1850)
Predicate Device:	TRIMAX RADIOGRAPHIC CASSETTE (510(k) number: K980722), IMATION Corp., 1 Imation Place, Oakdale, MN 55128

Description and Intended Use of Device

Ferrania LifeRay™ Cassettes are intended for use during diagnostic x-ray procedures to hold radiographic film in close contact with an x-ray intensifying screen and to provide a light proof enclosure for direct exposure of this film. The Cassettes are in a family of film sizes. The LifeRay™ KW Cassettes contain a window compatible with Kodak system, that permits data writing by a radiographic film marking system. The LifeRay™ WL Cassette is windowless.

Technological Characteristics

Radiographic cassettes are composed of:

- a light tight chamber for preventing radiographic film exposure,
- a compressible backplate material to assure intimate film-screen contact,
- a latching mechanism for removal and replacement of radiographic film,
- a patient oriented surface transparent to x-ray energy,
- lead shielding to prevent unwanted exposure to x-rays

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assembled in a robust support structure to assure durability.

Performance data

Voluntary standards to which the Ferrania LifeRay™ Cassettes conform are:
ANSI PH1.49 – 1995
ISO/FDIS 4090: 2000.

Conclusion

Based on the analysis of the comparison made between the LifeRay™ Cassettes and the predicate device, Ferrania S.p.A. concluded that the LifeRay™ Cassettes are safe, effective and perform as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2001

Ferrania S.P.A.
% Ms. Chantel Carson
Underwriters Laboratories
333 Pfingsten Road
NORTHBROOK IL 60062-2096

Re: K012373
LifeRay™ WL and KW Series Cassettes (Radiographic film cassette)
Dated: July 23, 2001
Received: July 26, 2001
Regulatory Class: II
21 CFR 892.1850/Procode: 90 IXA

Dear Ms. Carson:

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) 594-4639. 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 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,

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 (s)

Statement of Indications for Use

510(k) Number (if known) K012373

Device Name: **LifeRay™ WL Cassette**
LifeRay™ KW Cassette

Indications for Use:

Ferrania LifeRay™ Cassettes are intended for use during diagnostic X-ray procedures to provide a light-proof enclosure for direct exposure of radiographic film and to hold this radiographic film in close contact with an X-ray intensifying screen.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012373