2/19/99

K983314

510(k) Summary
Nycomed Amersham Imaging
Premica™-CT Contrast Media Delivery System
(per 21 CFR 807.92)

1. SUBMITTER NAME AND ADDRESS

Nycomed Amersham Imaging
101 Carnegie Center
Princeton, NJ 08540-9998

Contact Person: Ms. Kathy Patterson
Telephone: (847) 593-6300, Extension 341

2. DEVICE NAME

Proprietary Name:	Premica™-CT Contrast Media Delivery System
Common/Usual Name:	Automatic injector for contrast media
Classification Name:	Injector, contrast medium, automatic

3. PREDICATE DEVICE/S

MEDRAD® ENVISION CT™ Injector System - K934086 74 - DXT

4. DEVICE DESCRIPTION

The Premica™-CT Contrast Media Delivery System consists of the following components:

- the console consisting of the pump, the main control panel, and the power supply,
- the remote control panel,
- the remote test injection trigger (handswitch), and
- associated cables.
- bottle insulators, and
- pedestal, connector, and wheels.

The printer is provided as an accessory.

5. INTENDED USE

The Premica™-CT Contrast Media Delivery System is indicated for the controlled automatic administration, on the venous side, of contrast media (CM) for computed tomography scan. The System consists of the Premica™-CT instrument, the Bottle Spike, the Day Set, the Patient Set, and accessories. The System is not intended for injection of CM for coronary arteriography, or for any other use for which the device is not indicated. The Premica™-CT Contrast Media Delivery System is not intended for use with children under 16 years of age.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Information supplied in this premarket notification includes descriptive information about the intended use, operation, and technological characteristics. A side-by-side comparison of the Premica™-CT Contrast Media Delivery System with the MEDRAD® ENVISION CT™ Injector System is provided in Table J-1. below.

Table J-1. Comparison of Premica™-CT Contrast Media Delivery System with the MEDRAD® ENVISION CT™ Injector System

Characteristic	Premica™-CT Contrast Media Delivery System	MEDRAD® ENVISION CT™ K934086
Indications		
Indicated for controlled administration of contrast media for computed tomography scans	Yes	Yes
Physical design		
Remote Panel	Yes	Yes
Weight (kg)	Pump 8 (17.6 pounds) Panel 1.7 (3.7 pounds)	Display 4.4 (9.7 pounds) Console 5.8 (12.8 pounds) Head Control 3.0 (6.7 pounds)
Temperature Control	Bottle Insulators	Syringe heater
Single Patient Use Disposables	Patient Set	Syringe
Connecting Tubing	1.5 meters	60 inches (1.52 meters)
Access Types	Rigid and flexible	Rigid and flexible
Access Gauge	16 to 20	Not specified
Multiple Patient Use CM	Yes	No

Table J-1. Comparison of Premica™-CT Contrast Media Delivery System with the MEDRAD® ENVISION CT™ Injector System (Continued)

Characteristic	Premica™-CT Contrast Media Delivery System	MEDRAD® ENVISION CT™ K934086
Designed to prevent reuse of disposables?	Yes	No
Operational Characteristics		
Flow Rate (ml/s)	0.2 to 9.9	0.1 to 9.9
Injection Volume/Injection	0 to 300 ml	1 ml to syringe capacity
Maximum Injection Duration	10 s to 9 min 59 sec; Depends on injection volume	Up to 33:20; Depends on volume, rate, and syringe size
CM Container Volume (ml)	0 to 500	Syringe sizes: 125 or 200 ml
Air Sensor	Yes (One for each bottle and one for the Patient Set)	No (Requires monitoring by the Operator)
Pressure Sensor	Yes	Yes
Pressure Limit	8 bar	Programmable from 25 to 300 psi in 5 psi increments
Test Injection Default	Default: 5 ml; 1 ml/s; increments of 0.1 ml/s	Default: 5 ml; 1.5 ml/sec; Volume: 1 - 10 ml; 1 ml increments Flow rate: 0.1 ml/sec to 9.9 ml/sec in 0.1 ml increments
Injection Capabilities	Up to 2 phases	1 to 8 phases
Interphase Delay (sec)	0-99	Optional
Protocol Storage	Up to 100 of 2 phases each	Up to 50 of 8 phases each
Saline Flush	Yes	No
Audible Scan Delay Signal	0 to 99 sec	0 to 99 sec

The major differences between the two systems are the ability of the Premica™-CT to be used for multiple patients without changing the reservoir of contrast medium, and System design which prevents disposables reuse. Nycomed Amersham Imaging has conducted testing to demonstrate that these differences do not raise new issues of safety and effectiveness. Bacteriological testing demonstrates that

normal use of the disposables of the Premica™-CT System does not introduce contamination into the contrast. Sets are not susceptible to microbial contamination when the System is used according to instructions for normal operation. Studies also demonstrate that the risk of cross contamination from an infected patient is negligible since the retrograde migration of the microorganisms and viruses was limited solely to the distal end of the Patient Set. The design of the Bottle Spike prevents re-use since the tip breaks off within the bottle upon Spike removal. Software control prevents re-use of the Day Set and Patient Set, past their intended durations of use. Validation activities demonstrate that the System fulfills this specification.

Nycomed Amersham Imaging believes that the information provided within this premarket notification and summarized above demonstrates that the Premica™-CT Contrast Media Delivery System is substantially equivalent to the MEDRAD® ENVISION CT™ Injector System. Testing demonstrates that the procedural difference, specifically multiple dose versus single dose, is safe and raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Nycomed Amerham Imaging, Inc.
c/o Rosina Robinson, RN, MED, RAC
Senior Staff Consultants
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K983314
Premica™ CT Contrast Media Delivery System
Dated: January 6, 1999
Received: January 7, 1999
Regulatory class: II
21 CFR 870.1650/Procode: 74 IZQ

Dear Ms. Robinson:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. 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): K983314

Device Name: Nycomed Amersham Imaging Premica™-CT Contrast Media Delivery System

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

David h. Sorrm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983314

Over-The-Counter Use ____