NOV 0 9 2001

K013548

October 24, 2001

Subject: 510(k) Summary of Safety and Effectiveness Information for the Standard Imaging IVB 1000 Well Chamber

Proprietary Name: Standard Imaging IVB 1000 Well Chamber

Common Name: Ion Chamber

Classification: Class II – 21CFR892.5700, 90JAQ or
Class I – 21CFR892.5650, 90IWJ
Class I – 21CFR892.1940, 90LHO

Panel: Radiology

Contact Person: Raymond Riddle, Vice President, Regulatory Affairs

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Standard Imaging IVB 1000 Well Chamber is substantially equivalent to the Standard Imaging HDR 1000 Plus/ IVB 1000 Well Chambers, which were cleared by FDA with 510(k) premarket notification K001825.

The Standard Imaging IVB 1000 Well Chamber is a well-type chamber. It is specifically designed to measure the amount of radiation of high-dose-rate (HDR), low-dose-rate (LDR) and intravascular (IVB) brachytherapy (gamma and beta) sources, with the appropriate calibration from an accredited dosimetry calibration laboratory. Sources must be measured using the appropriate and specific source holder as described in the IVB 1000 labeling. To check the bremstralung component of a source, the X-Ray Contamination Test Tool, an accessory to the IVB 1000, should be used.

It is recommended that the chamber be calibrated every two years, as is standard practice for other ionization chambers. Initially, the calibration factor is given in the calibration report from an Accredited Dosimetry Calibration Laboratory (ADCL).

The measurement of brachytherapy sources requires an electrometer with a calibrated scale for measuring currents in the range from 10^{-12}A to 10^{-7}A. Alternatively, a calibrated charge scale may be used with timed runs. If integral charge techniques are used with the time determined by the HDR irradiator timer, the contribution from the source transit-time should be taken into account.

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The IVB 1000 Well Chamber has a vent hole to maintain the internal air at ambient atmospheric pressure. Thus, the readings obtained must be corrected for ambient temperature and pressure to the temperature and pressure of calibration (22° C and 760 mm Hg) at "normal" relative humidity (50% ± 25%non-condensing) in the usual accepted manner. The IVB 1000 has available different inserts for IVB, HDR, LDR and X-Ray contamination measurements.

The IVB 1000 Well Chamber has a conventional triax connector and cable to be connected to a suitable electrometer. A bias of 300 volts must be applied to the electrometer low-impedance connection relative to chassis ground. The voltage polarity effect is less than 0.1%. If desired, a second bias level of 150 volts can also be used to determine the ionic recombination loss at 300 V.

The Standard Imaging IVB 1000 Well Chamber was designed to comply with the limited applicable portions of the following voluntary standards:

1. IEC 601-1: 1988 - Medical Electrical Equipment
2. IEC 60731: 1997 – Medical Electrical Equipment – Dosimeters with ionization chambers used in radiotherapy.

The Standard Imaging IVB 1000 Well Chamber and the predicate Standard Imaging HDR 1000 Plus and IVB 1000 Ion Chambers are substantially equivalent in design concepts, technologies, materials and intended uses. The Standard Imaging IVB 1000 Well Chamber has been validated through calibration testing conducted by the University of Wisconsin – Madison, Department of Medical Physics Accredited Dosimetry Calibration Laboratory.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Raymond T. Riddle, PE
Vice President, Regulatory Affairs
Standard Imaging™, Inc.
7601 Murphy Drive
MIDDLETON WI 53562-2532

Re: K013548
Trade/Device Name: Standard Imaging IVB 1000 Well Chamber
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: 90 KPT
Dated: October 24, 2001
Received: October 24, 2001

Dear Mr. Riddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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

NOV 0 9 2001

510(k) Number (if known): K013548

Device Name: Standard Imaging IVB 1000 Well Chamber

Indications For Use:

The Standard Imaging IVB 1000 Well Chamber is a well-type chamber. It is specifically designed to measure the amount of radiation of high-dose-rate (HDR), low-dose-rate (LDR) and intravascular (IVB) brachytherapy (gamma and beta) sources, with the appropriate calibration from an accredited dosimetry calibration laboratory. Sources must be measured using the appropriate and specific source holder as described in the IVB 1000 labeling. To check the bremstralung component of a source, the X-Ray Contamination Test Tool, an accessory to the IVB 1000, should be used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013548