NOV 1 3 2008

K083035

Attachment 5 - 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter:

Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Contact: Suzanne Schwaller, Regulatory Affairs Associate
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Prepared: October 10, 2008

Common or Usual Name:	Patient Radiation Dosimeter
Proprietary Name:	DVS, Dose Verification System
Classification Name:	System, Radiation Therapy, Charged-Particle, Medical Dosimeter, Ionizing Radiation, Implanted
Manufactured By:	Sicel Technologies, Inc. 3800 Gateway Centre Blvd. Suite 308 Morrisville, NC 27560 Phone: (919) 465-2236 Fax: (919) 465-0153

Predicate Device(s):

Sicel Technologies, Inc.
K052118, K061051, K071399, K080004
DVS, Dose Verification System

Device Description:

The DVS, Dose Verification System consists of four sub-systems: the DVS Implantable Dosimeter for measuring radiation dose *in vivo*, the DVS Insertion Tool for implanting the dosimeter during percutaneous procedures, the DVS Reader System (Wand and Base Station) for powering the dosimeter and providing a user interface when taking dose measurements, and the DVS Data System (Plan and Review Software and Dosimetery Database) for storing and reporting patient data and for storing dosimeter information. The dosimeters use a MOSFET, Metal Oxide Semiconductor Field Effect Transistor, as a sensing mechanism. The dosimeter is factory calibrated and powered by the Reader Wand utilizing electromagnetic energy. The dosimeter contains a transmitter, to transmit threshold voltage readings to the reader. It is radioopaque and thus registers on computed tomography scans as a point of interest whereby a point dose may be determined. Patients are implanted prior to radiotherapy. Information on the patient's therapy, dose planning, point dose at the dosimeter, dosimeter serial number and calibration files are entered into the Plan and Review software and stored in the Dosimetry Database. At each therapy fraction the dosimeter is read pre- and post-therapy using the Reader Wand and Base Station. This translates into a daily fractional dose. The patient's daily and cumulative dose may be reviewed via the Plan and Review software. Because the Plan and Review software and Dosimetry Database are designed to be stored on a server, multiple users may be logged into the system at any one time. Reports on the patient's daily and cumulative dose history may be printed using the Plan and Review software.

Indication for Use:

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

The DVS system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

Comparison with Predicate Device:

The intended use of this SICEL DVS is identical to the predicate device, the DVS Dose Verification System in K052118, K061051, K071399 and K080004. The indications for use of the SICEL DVS also are the same.

The technological features of the SICEL DVS Patient Dose Verification System are the same as the predicate including the use of MOSFET technology and the energy sources measured. The principles of operation are the same as the predicate and there are no changes in control mechanisms. The materials of the dosimetery have not changed and the dosimeter sterilization method is the same. The insertion tool design, materials, and sterilization are the same. The Reader design and performance specifications are the same and have not changed.

The primary difference between the predicate device and the modified device is the addition of the DVS HFT dosimeter to the DVS System. This change involves a change to the performance specifications of the predicate standard dosimeter; specifically, a change has been made to the dose ranges and corresponding accuracies allowing for the use of the dosimeter with hypofractionated radiation treatment plans. The other changes to the system included software, labeling and manufacturing process changes which support the addition of the DVS HFT dosimeter option.

Furthermore, verification and validation testing based on the risk analysis, provided information sufficient to determine that the modifications did not have an effect on safety or efficacy and demonstrated that the device met acceptance criteria based on performance specifications. The testing demonstrated that the modified device is substantially equivalent to the predicate device and performs as well as the predicate device. The verification and validation results are provided within the 510(k).

Thus, the DVS, Dose Verification System is substantially equivalent to the DVS, Dose Verification System (K052118, K061051, K071399, K080004).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

Ms. Suzanne Schwaller
Regulatory Affairs Associate
Sicel Technologies, Inc.
3800 Gateway Centre Blvd., Suite 308
MORRISVILLE NC 27560

Re: K083035
Trade/Device Name: DVS, Dose Verification System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: NZT
Dated: October 10, 2008
Received: October 16, 2008

Dear Ms. Schwaller:

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 such 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 Section 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 6 – Intended Use Statement

510(k) Number (if known): K083035

Device Name: DVS, Dose Verification System

Indications for Use:

Intended Use

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

Indications for Use

The DVS system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083035