

Predicate Device(s):

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

JAN 23 2008

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 Dosimetry 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, and K071399. The indications for use of the SICEL DVS also are the same.

The technological features of the SICEL DVS Dosimeter are the same as the predicate including the use of MOSFET technology, the calibration method, dose range, and energy sources measured. The dosimeter performance specifications are the same and have not changed. The principle of operation is the same as the predicate. The tissue contacting materials are the same and the 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 Data System is the same and has not changed.

The primary difference between the predicate device and the modified device is the change to the dosimeter's potting epoxy used to secure and position the electronics within the biocompatible glass capsule. Other changes include minor dimensional changes, minor changes to the electronics components, and minor changes to the Reader software and accompanying Operator's Manual. Details of the substantial equivalence comparison are provided.

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 pre-determined 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).



JAN 23 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Tammy B. Carrea  
Vice President, Regulatory Affairs  
Sicel Technologies, Inc.  
3800 Gateway Centre Boulevard, Suite 308  
MORRISVILLE NC 27560

Re: K080004

Trade/Device Name: Dose Verification System Patient Dosimetry System  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: NZT  
Dated: December 31, 2007  
Received: January 2, 2008

Dear Ms. Carrea:

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.

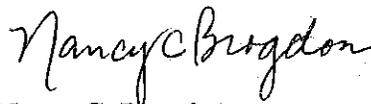
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K080004

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.

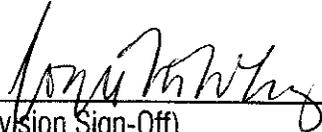
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
510(k) Number K080004