

SEP 5 1996

# Mc MAHON

## MEDICAL INCORPORATED

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510(k) Summary

K961105

Applicant:

McMahon Medical, Inc.  
9823 Pacific Heights Blvd.  
Suite V  
San Diego,  
CA 92121

Telephone: (619) 450-0507  
FAX: (619) 450-1066

Contact person:

Mr. M. McMahon, President

Product Name:

Trade Name. Skin Dose Monitor, may be abbreviated to SDM.  
Common Name. Patient Dosimeter.  
Classification Name. (To be entered by Dr. Ralph Shuping at FDA)

Legally marked device to which equivalence is being claimed:

In Vivo Dosimeter

Manufactured by:

Sun Nuclear Corp.  
425-A Pineda Court  
Melbourne,  
Florida 32940-7508

#### Description of the Skin Dose Monitor

The Skin Dose Monitor consists of the model 104-101 Instrument complete with couch mounting bracket and QA Test Box. The 104-120 limited re-use sensor is also part of the system.

The sensor consists of a scintillating crystal which partially converts absorbed ionizing radiation into visible light. A length of radio translucent optical fiber transports the emitted light to the 104-101 instrument. The light is converted to an electrical current within the instrument and following scaling and integrating, is displayed on an LCD display in Grays or Rads. The instrument is battery powered and the displayed reading is retained when power is switched off.

#### Intended use of the Skin Dose Monitor

The Skin Dose Monitor is designed to measure skin dose during X-Ray diagnostic and interventional procedures.

Comparison of technical features with those of the predicate device.

The differences between the Skin Dose Monitor (SDM) and the In Vivo Dosimeter (IVD) are due to the former being used during X-Ray diagnosis and the latter product being used during Radiation Therapy. Both have a skin mounted sensor, in the case of the SDM this is a crystal where the IVD uses a diode. Both are optimized for the radiation energy being measured. In the case of SDM the manufacturer provides a means of fixation of the sensor to the patients skin where the IVD manufacturer leaves this matter to user innovation.

Coupling to the processing and display instrument is by optical fiber for the Skin Dose Monitor and by cable for the IVD. The optical fiber was selected for its radio translucent qualities but provides an incidental advantage of total electrical isolation of the patient from the main instrument.

The SDM, which is designed for couch mounting is small, compact and robust. It is powered by batteries and has the minimum of intrusive user controls. The IVD which is intended for mounting remote from the patient includes a number of software based functions to aid data logging, etc., and is mains powered raising added safety issues.

None Clinical Performance assessment.

Extensive measurements have been carried out to ensure the SDM neither generates Electromagnetic Radiation, or is affected by levels of electromagnetic radiation found in the typical radiological examination room. Comparisons have been made with industry standard Ion chamber and diode dose measuring systems to confirm the skin dose monitor precision and stability are sufficient for its intended use. These include energy and dose rate response, and long term stability with expected changes in ambient temperature. Although as is the case with the IVD precision of 1% could be achieved with careful local physics calibration 10% is considered acceptable for skin dose monitoring and attempts to achieve further improvements at the cost of user convenience are not seen as justified.

Clinical Performance Assessment.

This has been restricted to confirming the effectiveness and safety of the adhesive fixing disc.

The sensor was fixed for prolonged periods to a number of volunteers. It was inspected for adhesion prior to removal, ease of removal was noted along with any skin discoloration. These tests confirmed those carried out by the material manufacturer, in that the sensor was adequately held in place for a number of hours, could be removed without undue discomfort and showed no signs of causing skin irritation.

Conclusions drawn from clinical and non-clinical tests.

The tests carried out were designed to confirm that differences between the Skin Dose Monitor and the predicate device, The In Vivo Dosimeter, would not compromise safety or effectiveness.

The main differences are explained by the intended use being for diagnostic rather than therapy dose monitoring. They were shown to enhance the effectiveness for the intended application and provide added user convenience.

The SDM design was also shown to have significant safety advantages.



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Mr. Martin McMahon  
President  
McMahon Medical Incorporated  
9823 Pacific Heights Blvd., Suite V  
SAN DIEGO CA 92121

FEB 19 2013

Re: K961105  
Trade/Device Name: Skin Dose Monitor  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: OWB and JAA  
Dated: June 27, 1996  
Received: June 28, 1996

Dear Mr. McMahon:

This letter corrects our substantially equivalent letter of September 5, 1996.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

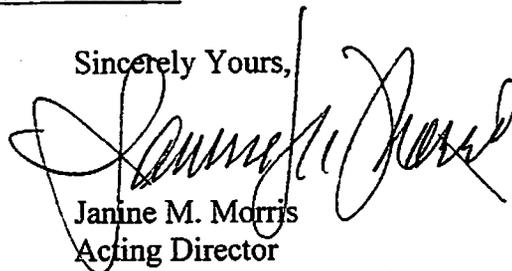
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K961105

Device Name: Skin Dose Monitor

**Indications For Use:**

Although intended primarily for use during Radiological Interventional and Special Procedures, the Skin Dose Monitor can be used whenever there is an interest in knowing patient skin dose.

The primary purpose of the product is to monitor beam entry skin dose within the radiation beam, where there may be a risk of skin burns or cancers due to extremely high doses.

In these situations the beam direction is fixed for a major part of the procedure and the sensor siting is obvious.

If the Skin Dose Monitor is to be used for other applications such as dose monitoring of a pregnant woman during general radiological procedures or monitoring doses during fluoroscopic guided surgery, the sensor site may be less obvious. Under these circumstances the sensor might be mounted on the X-Ray collimator face.

The real time display of dose may be used to indicate the need to take action to avoid excessive dose to one area of skin by changing the beam direction. The rate indicating LED provides a means to take action which will keep dosage per minute during fluoroscopy at the minimum level needed to ensure acceptable images.

The Skin Dose Monitor is also an effective tool for use during staff training or when benchmark protocols are being established for new procedures.

Contra indications for use are when the radiation energy or dose rate being used fall outside the Skin Dose Monitor's specification, or where the small artefact in the image (1 sq. mm), due to the sensor, is unacceptable.

Attention is drawn to the user for the need to gas sterilize sensors between applications in accordance with local infection control practice.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*David G. Seymour*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K961105

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*[Handwritten mark]*