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K042698

OCT 2 2 2004

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Unfors Instruments, Inc.
2.	*Address:*	123 Litchfield Road New Milford, CT 06776
3.	*Telephone:*	860-355-2588
4.	*Contact Person:*	Patrick R. Pyers
5.	*Date Prepared:*	September 28, 2004
6.	*Registration Number:*	3004099922

B. Device

1.	*Name:*	Unfors PSD
2.	*Trade Name:*	Patient Skin Dosimeter
3.	*Common Name:*	Patient Skin Dosimeter
4.	*Classification Name:*	System, X-Ray, Fluoroscopic, Image-Intensified
5.	*Product Code:*	JAA
6.	*Class:*	II
7.	*Regulation Number:*	892.1650

C. Identification of Legally Marketed Devices

1.	*Name:*	Skin Dose Monitor (SDM)
2.	*K Number:*	K961105
3.	*Date Cleared:*	September 5, 1996

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D. Description of the Device

The Unfors Patient Skin Dosimeter (PSD) is a skin dosimeter to measure patient entrance skin dose in real time during fluoroscopy / computerized tomography (CT) procedures. The PSD can be equipped with 1-4 sensors.

The PSD consists of several small (1-4) sensors on cables connected to a display unit. The sensors can be placed anywhere on the body and will leave a minimal footprint on the X-Ray image.

The 1-4 sensors can independently measure dose. The PSD has two keys, ON/OFF and SELECT. The SELECT key is used to step through measured values and to enter software menus. An audio-visual 4 level warning system indicates to the user when specific dose levels are reached.

The PSD is provided non-sterile and is *not* programmable. Thus, there is no software to be concerned with.

Accessories that can/may accompany the PSD are an aluminum holder to hold the PSD to a patient side rail and a hard case to protect the PSD during shipping and storage. These are the only two accessories.

E. Intended Use Statement

The Unfors Patient Skin Dosimeter (PSD) is a skin dosimeter to measure patient entrance skin dose in real time during fluoroscopy / computerized tomography (CT) procedures. The PSD can be equipped with 1-4 sensors.

F. Technological Characteristics Summary

Similarities between both devices are the following:

- Mounting Bracket
- Indications for Use
- Prescription Device
- Multi-Use
- Non-Sterile
- Environment (X-Ray Procedures)
- Sensors

UNFORS INSTRUMENTS, Inc.
123 Litchfield Road
New Milford, CT 06776, USA
Phone: (866) 4UNFORS, (860) 355-2588
Fax: (860) 350-2664
E-mail: info@unfors.com, www.unfors.com

- Cables
- Read-out Instrument
- Diagnostic Purposes
- Battery Powered

Differences are the PSD has 1-4 sensors, whereas the SDM has one sensor. SDM uses a fiber optic cable which is prone to mechanical stress. The life-time of the SDM Sensor is a few examinations and then disposed.

The differences are considered minor and do not raise safety concerns.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2004

Mr. Patrick R. Pyers
President
Unfors Instruments, Inc.
123 Litchfield Road
NEW MILFORD, CT 06776

Re: K042698
Trade/Device Name: Patient Skin Dosimeter
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: 90 JAA
Dated: September 28, 2004
Received: September 30, 2004

Dear Mr. Pyers:

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 (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 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.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" (21 CFR 807.97). 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) 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

Indications for Use

510(k) Number (if known): *To be determined* K042698

Device Name: Patient Skin Dosimeter

Indications for Use:

- Measure patient entrance skin dose in real time during fluoroscopy / computerized tomography (CT) procedures. It can be equipped with 1-4 sensors.

Prescription Use _X_ ~~AND~~/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH Office of Device Evaluation (ODE)

David B. Hoyt

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042698