K091364

510(k) Summary DEC 11 2009

1. Administrative Information

Reason for Submission:

510(k) Notification for *dicomPACS*® *5.2 and dicomPACS DX-R*® *1.6*

Submitter:

Address:	Oehm und Rehbein GmbH Waldemarstr. 20 g/h 18057 Rostock GERMANY
Establishment Registration Number:	3006542593
Submission contact person:	Mr. Wolfgang Moeller
Contact telephone:	+49 381 2036 1295
Contact e-mail:	wolfgang.moeller@oehm-rehbein.de
Common device name:	PACS (Picture Archiving and Communications System)
Classification:	Class II
Regulation no.:	892.2050
Product code:	LLZ
US Agent:	Alan Schwartz
US Agent company:	mdi Consultants, Inc.
US Agent address:	55 Northern Blvd. Suite 200, Great Neck, NY 11021
US Agent telephone:	516-482-9001

Substantial equivalent device:

Device Name(s):	*dicomPACS*® 5.2 *dicomPACS*® DX-R 1.6
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Common Product Name:	Radiological Image Processing System

Predicate device:

Device Name(s):	*dicomPACS*® 5
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Common Product Name:	Radiological Image Processing System
510(k) Number:	K070618

2. Indications for Use

dicomPACS® DX-R can control X-ray generators. ***dicomPACS***® DX-R is not approved for the acquisition of mammographic image data.
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.
Functions to be carried out using ***dicomPACS***® and ***dicomPACS***® DX-R are, for example, but not limited to, adjustment of window leveling, rotation, zoom, and measurements.
dicomPACS® and ***dicomPACS***® DX-R are meant to be used by qualified medical personnel only. All users must be qualified to create and diagnose radiological image data.

3. Functional Comparison

The software comes in two varieties – as ***dicomPACS***® 5.2. and as ***dicomPACS***® DX-R 1.6. While ***dicomPACS***® DX-R 1.6 provides some functionality like generator control, CR/DR acquisition and raw data processing, ***dicomPACS***® does not have these functions. The following table gives you an overview which configuration provides which new functionality.

The functions as given in the previous Premarket Notification, K070618, remain valid. Please find the 510(k) for the previous Premarket Notification in Sec. 11-A of this submission.

There have been modifications since version 5 of the software. The following table provides a list of all modifications that have taken place between ***dicomPACS***® in version 5 and ***dicomPACS***® in version 5.2 and ***dicomPACS***® DX-R in version 1.6.

#:	Komponente:	dicomPACS®	dicomPACS® DX-R
1.	Viewer-dicomWeb	X	X
2.	Viewer-Prosthesis Module	X	X
3.	100% magnifying glass	X	X
4.	MPR (multi-planar reconstruction)	X	X
5.	Hanging protocol section area	X	X
6.	Generator Control [Accession No.: 0910034-000]	-	X
7.	CR/DR acquisition	-	X
8.	Raw data processing	-	X
9.	Image overlay configuration	-	X
10.	X-ray assistant	-	X
11.	Examination tree	-	X
12.	Virtual keyboard	-	X

Table 1: Modifications to different configurations

4. Significant Change

As layed out in the "List of Modifications" in Sec. 10 of this submission some of the current changes are significant according to the FDA memorandum #K97-1 "Deciding When to Submit a 510(k) for a Change to an Existing Device".
These significant changes are

No. 4 – Multiplanar Reconstruction (MPR),
No. 7 – CR/DR acquisition, and
No. 8 – Raw data processing.

5. Substantial Equivalence Conclusion

None of the modifications alter the Indications for Use in a significant way, nor the fundamental scientific technology, and do not introduce a fundamentally new scientific technology.

We therefore believe that the information presented in this Special 510(k) demonstrate that the product is safe for the patient, user, and bystander and does not raise any new questions regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Oehm und Rehbein GmbH
% Mr. Alan Schwartz
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

DEC 11 2009

Re: K091364
Trade/Device Name: *dicomPACS® 5.2 / dicomPACS®* DX-R 1.6
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 18, 2009
Received: December 2, 2009

Dear Mr. Schwartz:

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/ReportaProblem/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting 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): _____
Device Name: __*dicomPACS*® 5.2 / ***dicomPACS***® DX-R 1.6_____

Indications for Use:

dicomPACS® and ***dicomPACS***® DX-R are software systems for the administration, archiving, processing, improvement and compression of medical image data for diagnosis. The images are either acquired from imaging modalities via DICOM or imported directly. All images are archived in a database as DICOM compliant files. The data is displayed on a computer monitor for diagnosis. ***dicomPACS***® and ***dicomPACS***® DX-R also provides services for administering the data.
dicomPACS® DX-R can control X-ray generators. ***dicomPACS***® DX-R is not approved for the acquisition of mammographic image data.
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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091364