RRG/LLD 1/6/93
Rev. 2/6/96

Dreard premarket Notification 510(k)
Screening Checklist

510(k) Number & Device Name: ***ddR*Combi TRAUMA**_____
Company: **Swissray Medical AG**_____

Item	Present Yes	Present no	Needed Y/N ?
1. **General Information** (i.e., trade & classification name, Est. Reg. No. Device class, meets special controls or A performance standards, etc.)			
- **Reason for 510(k) – new device or modification**	☒	☐	☒
- Identification of legally marketed equivalent device	☒	☐	☒
- Truthful and accurate statement	☒	☐	☒
- SMDA 510(k) summary or statement	☒	☐	☒
2. **Proposed Labeling, Labels, Advertisements**			
- Description of new device/modification	☒	☐	☒
- Intended use statement	☒	☐	☒
- Diagrams, Engineering Drawings, Photographs	☒	☐	☒
- Indication for use Statement	☒	☐	☒
3. **Comparison of similarities / differences Legally marketed equivalent device** *Please provide tabular comparison of specifications and Features to one of your predicate devices utilizing one Comparison chart*	☒	☐	☒
- Equivalent Device Labeling, Labels, Advertising	☒	☐	☒
- Intended use of equivalent device	☒	☐	☒
4. **List all patient contracting materials in new device**	☒	☐	☒
Comparison of materials to equivalent device	☒	☐	☒
5. **Biocompatibilität information / data for patient** Contacting materials, or certification – identical material / formulation	☒	☐	☒
6. **Performance data : bench data**	☒	☐	☒
Please provide phantom data for resolution, gray scale and Contrast, also provide full MTF curve data,			
Animal data	☐	☒	☐
Clinical data	☒	☐	☒
7. Sterilization information	☐	☒	☐
8. Harware / Software validation & verification	☒	☐	☒
9. If class III, class III Certification & Summary	☐	☒	☐
10. If kit, kit certification	☐	☒	☐
11. Provide prescription labeling in your User manual	☒	☐	☒
12. Your device is consider a Tier 1 device and requires MFR statement of SE and DRAERD Checklist	☒	☐	☒

1. General Information

1.1 Name and address of manufacturer

Swissray Medical AG
Turbistrasse 25 ... 27
CH-6280 Hochdorf
Switzerland

Primary Contact

	Swissray America Inc. Submission correspondent
Resp.	Mr. John Monahan
Date	2005-03-15
Address	1180 Mclesterstreet Unit #2
City	Elizabeth
ZIP Code	NJ 07201
Country	USA
Phone	001 908 35 30 971
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E-mail	JMonahan@swissray.com

1.2 Establishment registration number

8043768

1.3 Classification, common and proprietary names of the device

Classification Name: Stationary X-ray system, 21 CFR 892.1680
Common names: Stationary X-ray system
Proprietary Names: *ddR*Combi TRAUMA

*ddR*Combi TRAUMA components

- X-ray detector AddOn-bucky
- Collimator
- X-ray tube
- X-ray Generator and eXpert 4000 control desk + application selection
- Movable Stand
- Ceiling suspension
- Height adjustable fix table IGS TRAUMA
- Workstation (Image processing)

1.4 Class

Class II

1.5 Applicable Standards

Code of Federal Regulations Title 21 subchapter J – Radiological Health, Part 888 Parts 1020.10, 1020.30, 1020.30, 1020.31 and 1020.40

Note: Swissray is not a manufacture of video monitors and film printers

IEC / EN 60601-1 Electrical Safety
UL 60601-1 and CSA 22.2 No. M601.1
IEC / EN 60601-2-32 Mechanical safety
IEC / EN 60601-1-2 EMC
IEC / EN 60601-1-3 X-ray Protection
IEC / EN 60601-2-7 X-ray Generator
IEC / EN 60601-1-4 Risk analysis for programmable medical electrical systems
IEC / EN 60601-2-28 SAFETY OF X-RAY SOURCE ASSEMBLIES AND X-RAY TUBE ASSEMBLIES FOR MEDICAL DIAGNOSIS
DICOM 3.0
HL-7 Data Exchange Standard
IHE
ARC / NEMA Data Exchange Standard

Quality System ISO EN 9001:2000 and ISO EN 13485:2000 (CAN + ECC)

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

Swissray Medical AG
% Mr. John Monahan
QA Manager
Swissray Int., Inc.
1180 Mclester Street, unit #2
ELIZABETH NJ 07201

AUG 23 2013

Re: K050718
Trade/Device Name: ddRCombi Trauma
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 16, 2005
Received: April 6, 2005

Dear Mr. Monahan:

This letter corrects our substantially equivalent letter of May 26, 2005.

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/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/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: **K050718**

Device name : ***ddR*Combi Trauma**

Indication for Use

The Swissray Medical AG Direct Digital X-ray Radiography diagnostic system class II (stationary) ***ddR*Combi Trauma** is a further development of the **AddOn Multi System**. This system can be used in a standard X-ray room and suitable for emergency / Trauma X-ray rooms.
The ***ddR*Combi Trauma** is intend for applying general radiography on a patient in a supine, seated or standing position.
With the fix height adjustable patient table and the new flexible detector positioning, the patient must be no more repositioned for the most X-ray applications.

The ***ddR*Combi Trauma** allows the operator a full control of the Patient data, positioning, X-ray parameter (automatic by organ selection or manual settings), exposure control and image quality.
The operator can use the following image control functions without losing the original exposure:

- Brightness, contrast, shape, rotate, zoom, inverse, cut off etc.
- Storage function (PACS, HL 7) included all X-ray parameter and patient information

The ***ddR*Combi Trauma** allows the operator to print images (DICOM format) in background on a laser printer (the most printer suppliers are available) or CD-ROM.
The major system components are:
fix height adjustable patient table, X-ray generator, X-ray tube, Collimator, stand, ceiling suspension, digital AddOn bucky (4 CCD cameras), Image processing software and monitors.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (DOE)

Prescription Use or Over-The Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050718