This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: March 21, 2014

Manufacturer: Philips Healthcare (Suzhou) Co., Ltd.
No. 258, ZhongYuan Road, Suzhou Industrial Park, 215024 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
Establishment Registration Number: Not registered yet

Contact Person: Gordon Shu
Regulatory Affairs Manager
Phone: +86-512-67336804
Fax: +86-512-68018677
E-mail: Gordon.Shu@philips.com

Trade Name: DuraDiagnost
Common Name: Digital Diagnostic Radiographic System

Classification:
Classification Name: Stationary X-Ray System
Classification Regulation: 21 CFR §892.1680
Classification Panel: Radiology
Device Class: Class II
Classification Product Code: KPR (System, X-Ray, Stationary)
Subsequent Product Code: MQB (solid state x-ray imager (flat panel/digital imager)

Predicate Device 1:
Trade Name: Brivo XR385, Digital Diagnostic Radiographic System
Manufacturer: GE MEDICAL SYSTEM, LCC
510(k) Clearance: K103448 (August 12, 2011)
Classification Regulation: 21 CFR, Part 892.1680
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Device Class: Class II
Product Code: KPR
<table>
<thead>
<tr>
<th>Predicate</th>
<th>Device</th>
<th>Trade Name:</th>
<th>Philips BuckyVision</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:</td>
<td></td>
<td>Manufacturer:</td>
<td>Philips Medical Systems, Inc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>510(k) Clearance:</td>
<td>K982795 (November 24, 1998)</td>
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<td></td>
<td></td>
<td>Classification Regulation:</td>
<td>21 CFR §892.1680</td>
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<td></td>
<td>Device Class:</td>
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<tr>
<td></td>
<td></td>
<td>Product Code:</td>
<td>KPR &amp; MQB</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Predicate</th>
<th>Device</th>
<th>Trade Name:</th>
<th>ddRVersa™ Motion</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:</td>
<td></td>
<td>Manufacturer:</td>
<td>Swissray Medical AG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>510(k) Clearance:</td>
<td>K123005 (December 7, 2012)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Classification Regulation:</td>
<td>21 CFR §892.1680</td>
</tr>
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</tr>
<tr>
<td></td>
<td></td>
<td>Device Code:</td>
<td>KPR &amp; MQB</td>
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</tbody>
</table>

### Device description:
The Philips DuraDiagnost Digital Diagnostic Radiographic System (DuraDiagnost) is a flexible digital radiography (DR) system that is designed to provide fast and smooth radiography examinations of sitting, standing or lying patients. The Philips DuraDiagnost consist of the following components: Tube column with X-ray assembly, wall stand with detector carrier, patient table with detector carrier and floating table top, high voltage generator, and acquisition and reviewing workstation for post-processing, storage and viewing of images. Images may be transferred via a DICOM network for printing, storage and detailed review.
Indications for Use:
The DuraDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Summary of the Technological Characteristics & Fundamental Scientific Technology:
The components of the Philips DuraDiagnost employ similar basic construction and fundamental scientific technology as provided with the currently marketed and predicate GE Brivo XR385 and Philips BuckyVision with regards to the functionality of the following components: Integrated tube column, patient table with a floating table top, high-voltage generator, dual-focus rotation anode X-Ray tube, manual beam limiting device, digital detector, wall stand and workstation for images post-processing, storage and viewing (See the comparison Table provided below, comparing the Philips DuraDiagnost to the currently marketed predicate devices). The outcome of this comparison demonstrates that the minor differences in the technological characteristics do not affect the safety or effectiveness of the Philips DuraDiagnost when compared to the currently marketed and predicate devices.

The wireless portable detector (Model No. 3543EZ) of the Philips DuraDiagnost is identical to the wireless portable detector (Model No. 3543EZ) of the currently marketed and predicate ddRVersa™ Motion (K123005 – December 7, 2012) – Swissray Medical AG and is manufactured by Trixell. Therefore, both the wireless portable detector of the Philips DuraDiagnost and the wireless portable detector of the currently marketed and predicate ddRVersa™ Motion employ identical fundamental scientific technology.

Based on the information provided above, the Philips DuraDiagnost is considered substantially equivalent to the currently marketed and predicate device, GE Brivo XR385 (K103448 – August 12, 2011) and Philips BuckyVision (K982795 – November 24, 1998) in terms of fundamental scientific technology. With regards to wireless portable detector, the Philips DuraDiagnost is considered substantially equivalent to the currently marketed and predicate ddRVersa™ Motion (K123005 – December 7, 2012) – Swissray Medical AG in terms of fundamental scientific technology.
### Summary of Technological Characteristics of the Philips DuraDiagnost to the Currently Marketed Predicate Devices

<table>
<thead>
<tr>
<th>Feature</th>
<th>Currently marketed and Predicate GE Brivo XR385 (K103448)</th>
<th>Currently marketed and Predicate Philips BuckyVision (K982795)</th>
<th>Currently marketed and Predicate Swissray ddRVersa™ Motion (K123005)</th>
<th>Philips DuraDiagnost</th>
<th>Comparison Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design characteristic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-ray Tube</td>
<td>Toshiba E7843X</td>
<td>RO 1750 &amp; SRO 33100</td>
<td>Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips DuraDiagnost, since it is manufactured by the same manufacturer Trixell.</td>
<td>RO 1750 &amp; SRO 33100</td>
<td>Identical. The Philips DuraDiagnost and the currently marketed and predicate Philips BuckyVision both use the identical X-ray tube. Thus, demonstrating SE.</td>
</tr>
<tr>
<td>Max Tube Voltage</td>
<td>150kV</td>
<td>150kV</td>
<td>150kV</td>
<td></td>
<td>Identical. Thus, demonstrating SE.</td>
</tr>
<tr>
<td>Focal spot size</td>
<td>0.6mm/1.2mm</td>
<td>0.6mm/1.2mm</td>
<td>0.6mm/1.2mm</td>
<td></td>
<td>Identical. Thus, demonstrating SE.</td>
</tr>
<tr>
<td>Tube Max power</td>
<td>50KW</td>
<td>50KW/100KW</td>
<td>50KW/100KW</td>
<td></td>
<td>Identical. The Philips DuraDiagnost and the currently marketed and predicate Philips BuckyVision both use the identical X-ray tube. Thus, demonstrating SE.</td>
</tr>
<tr>
<td>Anode Type</td>
<td>Rotation</td>
<td>Rotation</td>
<td>Rotation</td>
<td></td>
<td>Identical. Thus, demonstrating SE.</td>
</tr>
<tr>
<td>Generator</td>
<td>Unknown</td>
<td>EMD Technologies, M-CABINET CXA 50kW, M-CABINET CXA 65kW, M-CABINET CXA 80kW</td>
<td>EMD Technologies, M-CABINET CXA 50kW, M-CABINET CXA 65kW, M-CABINET CXA 80kW</td>
<td></td>
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<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max Power</td>
<td>50kW</td>
<td>50kW/65kW/80kW</td>
<td>50kW/65kW/80kW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>KV range</td>
<td>40-150</td>
<td>40-150</td>
<td>40-150</td>
<td></td>
<td></td>
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<tr>
<td>Milliampere</td>
<td>0.02 mAs-512 mAs (with AEC control)</td>
<td>0.5 mAs-600 mAs (with AEC control)</td>
<td>0.5 mAs-600 mAs (with AEC control)</td>
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<table>
<thead>
<tr>
<th>Collimator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation Mode</td>
</tr>
<tr>
<td>Manual collimation</td>
</tr>
<tr>
<td>Shape of Beam</td>
</tr>
<tr>
<td>Detector</td>
</tr>
<tr>
<td>Type</td>
</tr>
<tr>
<td>X-ray Scintillator Material</td>
</tr>
</tbody>
</table>
| Image Area | 40.4cm x 40.4 cm | 42.5 cm x 42 cm | 42.4cm x 34.8cm (wireless) | 43cm x 43cm(Fixed) 42.4cm x 34.8cm (wireless) | Identical for Wireless Portable Detector. The Wireless Portable Detector of the Philips DuraDiagnost and
the currently marketed and predicate Swissray's
ddRVersatm Motion utilize identical image area. Thus
demonstrating SE.

Similar for Fixed Detector.

The slight differences between the image area of the Philips
DuraDiagnost and the currently marketed and predicate predicate
Philips BuckyVision and GE's Brivo XR385 are not anticipated
to significantly alter the diagnostic image quality. Thus,
demonstrating SE.

<table>
<thead>
<tr>
<th>Image Matrix Size</th>
<th>2048 x 2048</th>
<th>2874 x 2840</th>
<th>2866 x 2350 (wireless)</th>
<th>2874 x 2869 (Fixed)</th>
<th>2866 x 2350 (wireless)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philips DuraDiagnost 510 (K)</td>
<td>510(K) Summary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Source to Image Distance (SID)</td>
<td>Table: 50-110cm; Wallstand: 100-180cm</td>
<td>SID depends on different configurations, because BuckyVision is ceiling suspension X-ray system. Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips DuraDiagnost, since it is manufactured by the same manufacturer Trixell.</td>
<td>Table: 40-115cm; Wallstand: 110-245cm</td>
<td>The slight differences between the SID of the proposed DuraDiagnost and the currently marketed and predicate GE’s Brivo XR385 are not anticipated to significantly alter the application usage. Thus, demonstrating SE.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Analog / Digital (A/D) conversion</td>
<td>14 bits</td>
<td>16 bits</td>
<td>16 bits</td>
<td>16 bits</td>
<td></td>
</tr>
<tr>
<td></td>
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</tbody>
</table>
## External Connectivity

<table>
<thead>
<tr>
<th>DICOM</th>
<th>DICOM 3.0 compatible</th>
<th>DICOM 3.0 compatible</th>
<th>DICOM 3.0 compatible</th>
<th>DICOM 3.0 compatible</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips <strong>DuraDiagnost</strong>, since it is manufactured by the same manufacturer Trixell.</td>
<td>Same. Thus, demonstrating SE</td>
<td></td>
</tr>
</tbody>
</table>

## Software Platform

<table>
<thead>
<tr>
<th></th>
<th>Eleva workspot</th>
<th>Eleva workspot</th>
<th>Eleva workspot</th>
<th>Eleva workspot</th>
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</thead>
<tbody>
<tr>
<td>Unknown</td>
<td></td>
<td>Note: The currently marketed and predicate Swissray ddRVersa™ Motion (K123005 – December 7, 2012) is only used to demonstrate substantial equivalence to the wireless portable detector (model 3543EZ) of the Philips <strong>DuraDiagnost</strong>, since it is manufactured by the same manufacturer Trixell.</td>
<td>Same. The Philips <strong>DuraDiagnost</strong> and the currently marketed predicate Philips BuckyVision both use the same software platform. Thus, demonstrating SE.</td>
<td></td>
</tr>
</tbody>
</table>
Non-clinical performance testing performed on the Philips DuraDiagnost demonstrates compliance with the following International and FDA-recognized consensus standards and FDA Guidance documents:


- CFR 1020.30 Diagnostic x-ray systems and their major components.

- CFR 1020.31 Radiographic equipment.


• FDA draft guidance document entitled, “Pediatric Information for X-ray Imaging Device Premarket Notifications issued on May 10, 2012.”

Additionally, verification / validation tests have been performed to address intended use, the technical claims, requirement specifications and the risk management results. The test results demonstrate that Philips DuraDiagnost:

• Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents.
• Meets the acceptance criteria and is adequate for its intended use.

Therefore, the Philips DuraDiagnost is substantially equivalent to the currently marketed and predicate device, GE Brivo XR385 (K103448, Aug. 12, 2011) Philips BuckyVision (K982795-Nov.24, 1998) and ddrVersa™ Motion (K123005 - December 7, 2005) - Swissray Medical AG in terms of safety and effectiveness.

Clinical Performance Data:

Clinical study was not warranted to support this 510(k) submission, since substantial equivalence to the currently marketed and predicate devices was demonstrated with the following attributes:

• Design features;
• Indication for use;
• Fundamental scientific technology; and
• Safety and effectiveness.
The Philips DuraDiagnost is substantially equivalent to the currently marketed and predicate device GE Brivo XR385 (K103448, August 12, 2011) and Philips BuckyVision (K982795, November 24, 1998) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. With regards to the wireless portable detector, the Philips DuraDiagnost is considered substantially equivalent in terms of design and fundamental scientific technology to the currently marketed and predicate dDRVersaTM Motion (K123005 - December 7, 2005) - Swissray Medical AG.

Additionally, substantially equivalence was demonstrated with the following:

- Non-clinical performance (verification / validation) tests, which complied with the requirements specified in the international and FDA recognized consensus standards;

- Tests identified in the FDA device specific guidance document entitled, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices – August 6, 1999." The results of these tests demonstrate that the Philips DuraDiagnost met the acceptance criteria, provides similar diagnostic image quality when compared with the predicate devices and is adequate for its intended use.

- Tests identified in the FDA guidance document entitled, "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff – August 13, 2013." The results of these tests demonstrate that the Philips DuraDiagnost met the acceptance criteria with regards to wireless technology used in the wireless portable Detector and is adequate for its intended use.
June 12, 2014

Philips Healthcare (Suzhou) Co., Ltd.
% Mr. Gordon Shu
Regulatory Affairs Manager
No. 258, Zhong Yuan Road
Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K141381
Trade/Device Name: Duradiagnost
Regulation Number: 21 CFR 892.1680
Regulation Name: DuraDiagnost radiographic system
Regulatory Class: II
Product Code: KPR, MQB
Dated: May 20, 2014
Received: May 28, 2014

Dear Mr. Shu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
Device Name
DuraDiagnost

Indications for Use (Describe)
The DuraDiagnost is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications.

Type of Use (Select one or both, as applicable)

- Prescription Use (Part 21 CFR 801 Subpart D)
- Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 70 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAS Staff@fda.hhs.gov

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