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K123603
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GE Healthcare
OEC® Brivo®
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 30, 2013
Submitter:	GE Healthcare Surgery 384 Wright Brothers Drive Salt Lake City, UT 84116
Primary Contact Person:	Gerald Buss Director Regulatory Affairs GE Healthcare Surgery Phone: (801) 517-6591 Fax: (414) 908-9249
Secondary Contact Person:	Jeff Wagner Regulatory Affairs Manager GE Healthcare Surgery Phone: (801) 517-6415 Fax: (801) 517-6566
Device: (Trade Name):	OEC® Brivo® 865 Plus, OEC® Brivo® 785 Essential, and OEC® Brivo® 715 Prime
Common/Usual Name:	Mobile Fluoroscopic Imaging System
Classification Names:	21 CFR 892.1650 Image-intensified fluoroscopic x-ray system
Product Code:	90OXO, 90JAA
Predicate Device(s):	K111551 OEC® 9800 / OEC® 9800 Plus
Device Description:	The OEC® Brivo® is a system used to assist trained physicians. The system is used to provide X-Ray images while the physician performs a medical procedure. Images from the system help the physician to visualize the patients' anatomy. This visualization helps to localize surgical regions of interest and pathology. The images provide real-time visualization and records of pre-surgical anatomy, in vivo-surgical activity and post-surgical outcomes. The system is composed of two primary physical elements. The first is referred to as the "C-Arm" because of its "C" shaped image gantry; the second referred to as the "Workstation" because this is the primary user interface to the system. The system is used in different surgical procedures.

Orthopedic Physicians may use the system to help perform hip replacements and reconstructions of badly fractured bones. Orthopedic Physicians may use the system to help perform hip replacements and reconstructions of badly fractured bones. The procedures that these surgeons perform are broadly referred to as "Clinical Applications". The system is controlled and run in a clinical environment.

The system employs X-Rays as its imaging technology. An X-Ray Generator located in the base of the C-Arm creates high voltage. High voltage is carried to the X-Ray tube across a set of cables. The X-Ray tube emits X-Rays that are directed toward the patient under the control of the operator. The Physician defines the desired view for the specific clinical procedure and directs the operator. The X-Rays pass through the patient and are captured by the image intensifier (II). Image intensifier images are captured by a camera and displayed on the image monitor located on the Workstation. The system operator and/or Physician view the images as they are displayed and they may choose to store the images for later review.

In order to perform these procedures different views of the human anatomy are required, so the system is designed with the ability to rotate and translate the C-Arm's image gantry to obtain different viewing angles. In addition since there is variation in thickness and density of the anatomy the operator has the ability to adjust the X-Ray Generator technique, image size and orientation to account for the anatomical differences.

Intended Use: *The OEC® Brivo® Mobile C-Arm X-Ray Products are designed to provide digital spot-film imaging and fluoroscopic image guidance for all adult and pediatric populations for orientations between patient anatomy and surgical instruments. The product is used for general surgical applications and musculoskeletal procedures to visualize, for example, implant localization/s or needle positions for aspirations, injections or biopsy. The OEC® Brivo® is not indicated for interventional use.*

Technology: The OEC® Brivo® (all models) is not indicated for interventional use (specifically vascular and cardiac applications) as is the OEC® 9800 (both models). As a non-interventional use device, the OEC® Brivo® does not require

the same capacity for long term or high capacity imaging that is necessary for the expanded use of the OEC® 9800.

The OEC® Brivo® does not support applications associated with vascular use, but does support the OEC® 9800 applications in general surgery, orthopedics, and for general surgical applications and musculoskeletal procedures to visualize for example implant localization/s or needle positions for aspirations, injections or biopsy

OEC® Brivo® does not include a 12" image intensifier option as does the OEC® 9800. The 9" version is sufficient for non-interventional use and has the same technology as the 9" option on the OEC® 9800.

The OEC® Brivo® x-ray tube is a fixed anode with lower power and cooling capacity than the rotating anode tube used in the OEC® 9800. The OEC® Brivo® tube operates on the same general technology and does not require the same capacity as the predicate for effective performance of its intended use. Because the OEC® Brivo® x-ray tube requires less kV to perform its intended use, the OEC® Brivo® generator is a reduced capacity version of the OEC® 9800 generator. Higher ratings are associated with interventional procedures not indicated for OEC® Brivo®

OEC® Brivo® is not offered with the same software options as OEC® 9800. Typical software options for interventional procedures for example, include digital cine, DSA, and Roadmapping.

OEC® Brivo® is not available in a motorized version and does not feature motion sensing and control capability associated with motorized use. Motorized versions are typically associated with interventional procedures and not required for successful performance of OEC® Brivo®'s intended use.

All the features of the OEC® Brivo® are substantially equivalent to the similar feature on the OEC® 9800. For these features, the OEC® Brivo® devices employ the same fundamental scientific technology as the predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests

The OEC® Brivo® complies with the voluntary and mandatory standards listed in Table 1 below. The following tests were performed:

- Software validation (Moderate level of concern) is the confirmation that the software design inputs and system functionality are consistent with the user needs and intended uses. Software validation occurred both during and at the completion of the product development cycle and ensured that all requirements were fulfilled.
- System verification methodology was hierarchal. When components such as software and hardware were completed, component level tests were executed. Upon completion of component testing, subsystem and then system verification were also performed. The Design Verification of the OEC® Brivo® confirms that design output meets design input requirements.
- Dose verification, image quality assessment and functional testing are included in system verification. A subset of this testing will be used to re-verify the device during manufacturing, installation and periodically through the product's life.
- Functional Product Simulated Use Testing ensures the system conforms to user needs and intended uses through simulated clinical workflow using step-by-step procedures that would be performed for representative clinical applications. Testing was performed by an orthopedic surgeon and trained clinical technicians confirming that OEC® Brivo® meets the user requirements and intended uses for the product.
- Safety testing was performed in laboratory settings by qualified technicians to confirm that the product met the requirements of the standards listed in Table 1 below.
- Performance Product Simulated Use Testing demonstrates that the fluoroscopic anatomical images provide clinically useful information through

visualization of anatomical details. Testing is performed by trained clinical representatives using anthropomorphic phantoms and confirmed that OEC® Brivo® produces clinically useful images.

- External Image Quality Evaluation was performed on human cadavers by orthopedic surgeons to provide a representative sample of images that a user may encounter during intended use. Evaluation of the images by orthopedic surgeons and clinical representatives demonstrated OEC® Brivo® produces useful images in a clinical environment.

Summary of Clinical Tests

The OEC® Brivo® is based on modifications to a cleared predicate device; these modifications resulted in a reduced number of available features as is consistent with the more limited indications for the OEC® Brivo® Mobile C-Arm X-Ray products. Because the OEC® Brivo® is based on modifications to a cleared device and because the indications are limited to surgical placement, clinical studies on living human patients were unnecessary to support substantial equivalence.

Conclusion: The performance testing described above demonstrates that the OEC® Brivo® product is safe, effective and performs, for its limited intended use, in an equivalent manner to the predicate device and in accordance with its labeling. For equivalent intended uses, the OEC® Brivo® is substantially equivalent in performance to the OEC® 9800.

Table 1 Product Standards Compliance

Standards No.	Standards Organization	Standards Title	Version	Date
21 CFR 1020.30-32	FDA	Federal Performance Standard for Diagnostic X-ray Systems	2012	2012
60601-1	UL	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	2005	2005

Standards No.	Standards Organization	Standards Title	Version	Date
60601-1	IEC	Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Ed. 3	2005
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests	Ed. 3	2007
60601-1-3	IEC	Radiation Protection in Diagnostic X-ray Equipment	Ed. 2	2008
60601-1-6	IEC	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Ed 3	2010
60601-2-28	IEC	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	Ed. 2	2010
60601-2-54	IEC	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Ed. 1	2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 17, 2013

GE Healthcare Surgery (GE OEC Medical Systems, Inc.)
% Mr. Gerald Buss
Director Regulatory Affairs
384 Wright Brothers Drive
SALT LAKE CITY UT 84116

Re: K123603
Trade/Device Name: OEC® Brivo® 865 Plus, OEC® Brivo® 785 Essential, and OEC® Brivo® 715 Prime
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO, JAA
Dated: April 12, 2013
Received: April 16, 2013

Dear Mr. Buss:

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 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. 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,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123603

Device Name: OEC® Brivo® 865 Plus, OEC® Brivo® 785 Essential, and OEC® Brivo® 715 Prime

Indications for Use: The OEC® Brivo® Mobile C-Arm X-Ray Products are designed to provide digital spot-film imaging and fluoroscopic image guidance for all adult and pediatric populations for orientations between patient anatomy and surgical instruments. The product is used for general surgical applications and musculoskeletal procedures to visualize, for example, implant localization/s or needle positions for aspirations, injections or biopsy. The OEC® Brivo® is not indicated for interventional use.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123603