

MAY 20 1996

## 9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

**Contact Person:** Gary Syring  
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**Date:** February 23, 1996

**Device/Trade Name:** ORCA  
**Common Name:** Ortho C-Arm

**Classification Name:** Image Intensified Fluoroscopic X-Ray System  
21CFR 892.1650

**Predicate Device:** K95 1765  
OEC Medical Systems Inc.  
Series 6600 Digital Mobile C-Arm

## 9.1 DESCRIPTION OF THE DEVICE:

The ORCA is a small image intensified fluoroscopic C-Arm, for imaging extremities in orthopedic applications. The ORCA is substantially equivalent to the Series 6600 Digital Mobile C-Arm, manufactured by OEC Medical Systems, Inc.

## 9.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The technical characteristics of the ORCA are substantially equivalent to the Series 6600 Digital Mobile C-Arm. A comparison table of technical characteristics follows.

<b>Feature</b>	<b>Predicate OEC MINI 6600</b>	<b>ORCA</b>
<b>Intended Use:</b>	Provide physician with general fluoroscopic visualization of the patient's extremities	Provide physician with general fluoroscopic visualization of patient's extremities
<b>X-Ray Source:</b>	Stationary Anode 0.25 mm focal spot 75 KVp/0.1 mA (7.5w) 40 cm SID	Stationary Anode 0.3 mm focal spot 80 KVp/0.7 mA (56w) 45 cm SID
<b>Image Information:</b>	Motorized Image Rotation 4 or 6 inch image intensifier 16 inch monitor	Digital Image Rotation 6 inch image intensifier 17 inch monitor
<b>Fluoroscopy:</b>	Manual Control - (combined KVp/mA) Automatic Exposure Rate Control	Manual Control - (combined KVp/mA) Automatic Exposure Rate Control
<b>Image Memory/Processing:</b>	640 X 510 X 10	512 X 512 X 12 1024 X 1024 X 12
<b>Image Handling Interface:</b>	Printer VCR Option DICOM 3 Parallel Port	Printer VCR Option DICOM 3 Parallel Port
<b>C-Arm Specification:</b>	30 cm Opening (with variance) 9 cm Source to Skin Distance (with variance) Manual mechanical positioning 200 degrees of orientation	35 cm Opening (with variance) 10 cm Source to Skin Distance (with variance) Manual mechanical positioning 270 degrees of orientation
<b>Scatter Radiation to Operator:</b>	< 5 mR/Hr	< 2 mR/Hr
<b>Power Requirements:</b>	110VAC, 1500 W	110VAC, 600 W

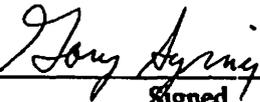
The x-ray technique factors of ORCA are higher than those of the predicate. However, the resulting extremity radiation exposure is below the 10 R/min limit of 21 CFR 1020.32.

The ORCA is designed to meet U.S. standards 21 CFR 1020.30 through 1020.32 with a variance for source to skin distance. The ORCA is designed to meet applicable International standards; IEC 601 - 1, IEC 601 - 1-1, IEC 601 - 1-2, IEC 601 - 1-3, IEC 601 - 2-7, IEC 601 - 2-28, IEC 601 - 2-32.

The typical operator radiation exposure is quite low, at less than 0.5 mR/hr @ 50 cm for Hand and less than 2.0 mR/hr @ 50 cm for Knee. The skin entrance dose of less than 5 R/min is a factor of 2x below the 10 R/min limit of 21 CFR 1020.32.

**9.3 CONCLUSION**

No new safety or effectiveness questions are raised by the ORCA device.

  
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Signed

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Gary Syring  
Printed Name

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Director, Regulatory Affairs  
Title



NOV 17 2011

Mr. Gary Syring  
Director, Regulatory Affairs  
Lunar Corporation  
313 W. Beltline Highway  
MADISON WI 53713

Re: K960907

Trade/Device Name: Mobile Orthopedic C-Arm  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image intensified fluoroscopic x-ray system, mobile  
Regulatory Class: II  
Product Code: OXO  
Dated: February 29, 1996  
Received: March 5, 1996

Dear Mr. Syring:

This letter corrects our substantially equivalent letter of May 20, 1996.

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 (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 contact 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 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,



Mary S. Pastel, Sc.D.  
Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 96 0907

Device Name: ORCA

Indications For Use:

The ORCA is a small image intensified fluoroscopic C-Arm, for imaging extremities in orthopedic applications. The ORCA Operator's manual contains the following statement:

"CAUTION: Federal Law (USA) restricts this device to sale and use by or on the order of a physician."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K960907

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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