

APR 12 1996

K955051

Premarket Notification

510(k) Summary

[As required by 21CFR 807.92(a)]

Trade Name: Nasa II C-arm
Common Name: C-arm
Classification Name: Mobile X-ray System

I certify that, in my capacity as President of Imaging Services, Inc., The Nasa II C-arm is equivalent to the OEC 901 and 902 model C-arms. Mechanically and electrically the Nasa II C-arm is as safe and effective as the OEC models 901 and 902. The difference between OEC's above models and the Nasa II is the imaging chain or CCD Camera and Camera Control Unit. The intended use for the Nasa II has not change and is not marketed as such.

The OEC 902 C-Arm frame, X-Ray Generator, X-Ray Control, Control Panel, Electrical Systems remain the same. Imaging Services, Inc. takes an OEC 902 and repaints it. We repair all mechanical brakes, replace the wheels with the new wheels rated for a greater weight, repair or replace motor drive assemblies with original or comparable replacement parts, repair all electronic systems, then calibrate the X-Ray generator to manufacture specifications using the OEC 902 Service Manual. Then we add a new 9/6 Image Intensifier and CCD Camera system. The CCD Camera System is calibrated to North American Imaging and Imaging Services Specifications. The ABS system utilizes original manufacturer's specifications, wiring and its electronic path remains the same.

The wiring of the CCD Camera system uses original wires provided by the original camera system which was deinstalled. The interface between the C-Arm and monitor cart also utilizes existing wiring as well as spares provided by OEC when the unit was originally manufactured.

Imaging Services, Inc. then tests the system to comply with all Federal, State and BRH standards. In no way does the final product effect the original X-Ray control as designed by OEC. As stated above, we continue to utilize the original C-Arm Generator and Control System as intended by OEC Dasonics.

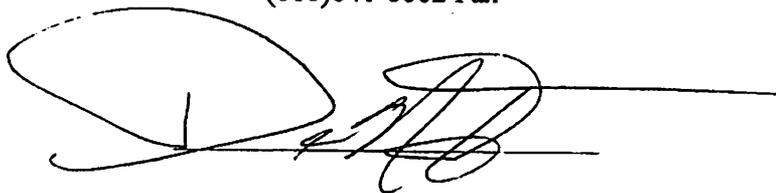
This upgraded version is designed only to provide a refurbished C-Arm with state of the art image quality. All of the results from this upgrade improve the final product delivered to the customer. Also with the CCD Camera upgrade and new Image Intensifier, the dynamic range of the C-Arm is increased to new C-Arm standards.

Patient dose is decreased by improving dynamic range and contrast/resolution is increased by the CCD Camera upgrade.

Imaging Services, Inc. follows all guidelines of Good Manufactures practices including serial number and calibration tracking and verification. All calibration equipment used by Imaging Services, Inc. is traceable to the National Bureau of Standards. Calibration specifications guidelines for x-ray control and generation are followed from the original Manufacturer's Service Manual. Imaging Chain Calibration Specifications/ Guidelines are followed by North American Imaging and Imaging Services, Inc. standards.

This product provides a high end, low cost refurbished system to customers who cannot afford a new C-Arm, while maintaining superior image quality as with a new C-Arm.

Imaging Services, Inc.
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(800)900-9729
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Dean N. Janes President

2/14/96

K 955 251

(Premarket Notification [510(k)] number)



Mr. Dean N. Janes
President
Imaging Services, Inc.
1037 North Lima Street
BURBANK CA 91505

NOV 17 2011

Re: K955251

Trade/Device Name: OEC 902 Nasa II CCD 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 15, 1996
Received: February 20, 1996

Dear Mr. Janes:

This letter corrects our substantially equivalent letter of April 12, 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