K070834

510(k) SUMMARY

MAY 18 2007

Company Name:	Omega Medical Imaging, Inc
Address:	675 Hickman Circle Sanford, FL 32771
Telephone No:	407-323-9400
Registration No.:	1052701
Contact person:	James A. Princehorn
Date Prepared:	1 February 2007
Device (trade) name:	*CS-Series* radiographic/fluoroscopy system
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	892.1650 and 892.1600
Device Class:	Class II
Device Code:	JAA, IZI
Common/usual name:	System, X-Ray, Fluoroscopic, Image-Intensified

Predicate device(s):

- Siemens AXIOM ARTIS U Angiography System (K040675)
- Philips Integris H5000 Angiography System (K984545)
- Omega Medical Imaging e-VIEW Fluoroscopy System (K062647).

Device description:

- The Omega Medical Imaging, Inc. *CS-Series* systems are comprised of an x-ray source/image receptor positioning device in a permanently floor mounted C-Arm configuration with options of either an elevating only or elevating/tilt patient table. The system may also be configure with a ceiling suspended "C" for bi-plane operation. The positioning of the source/receptor is achieved by motorized motions controlled by the operator. The imaging is achieved by way of an image intensifier/CCD camera with digital image processing.

Intended use:

- The Omega Medical Imaging, Inc. *CS-Series* systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

Safety information:

- The Omega *CS-Series* systems will comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega *CS-Series* systems will comply with the international safety standards IEC 60601-1, IEC 60101-1-2, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, and IEC 60601-2-32 .
- The Omega *CS-Series* systems will comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Software/Firmware

Omega Medical Imaging, Inc. manufactures the mechanical sub-systems for the CS-series systems. The control of these mechanical sub-systems is achieved without involvement of software or firmware. Omega Medical Imaging, Inc. obtains certified components from FDA registered suppliers that contain software/firmware. Omega Medical Imaging does not modify any of the software/firmware obtained by the suppliers. Omega Medical Imaging, Inc. conducts Vendor Audits of these suppliers to assure that these vendored components are suitable for this application.

Conclusion:

The Omega *CS-Series* systems do not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the *CS-Series* systems to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. James A. Princehorn
President
Omega Medical Imaging, Inc.
675 Hickman Circle
SANFORD FL 32771

MAY 18 2007

Re: K070834
Trade/Device Name: CS-Series Fluoroscopy System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: JAA and IZL
Dated: March 22, 2007
Received: March 27, 2007

Dear Mr. Princehorn:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070834

Omega Medical Imaging, Inc.
CS-series Radiographic/Fluoroscopic Systems

Indications for Use:

The Omega Medical Imaging, Inc. *CS-Series* systems are intended for use in radiographic/fluoroscopic applications including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070834