K100102

Omega Medical Imaging, Inc.

EXECTUTIVE 510(k) SUMMARY

AUG 31 2010

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:	22 July 2010
Device (trade) name:	CS-*series*-FP (SSXI) Fluoroscopy system
Common/usual name:	Image Intensified Fluoroscopic X-ray System
Classification Name:	Solid State X-ray Imager, Class II, 90 MQB Angiographic X-ray System, Class II, 90 IZI
Classification Panel:	Radiology
CFR Section:	892.1650 and 892.1600
Device Class:	Class II
Device Code:	90 MQB, 90 ~~IZI~~ OWB, JAA

Predicate device(s):

- GE Innova 2000 (K022322)
- Siemens Axiom Artis dFC (K021021)
- Philips Allura Xper FD10 F (K020055)
- Toshiba Infinix CCi/FPD (K052884)
- Omega Medical Imaging CS-series (K070834)

Device description:

- The Omega Medical Imaging, Inc. CS-*series*-FP (SSXI) systems incorporates a solid-state flat-panel detector (FPD) as an option to the cleared Omega Medical Imaging, Inc. CS-*series* fluoroscopy systems (K070834) in lieu of an image intensifier/CCD based imaging detector. The CS-*series* fluoroscopy single and dual plane x-ray imaging systems are configured with a floor mounted C-arm and a patient table. The dual plane systems incorporate a ceiling suspended C-arm. The image detector utilizes a cesium iodide scintillator coupled to an amorphous silicon TFT panel. The captured digital image is processed by the acquisition system which includes image processing, viewing functions, local storage, and DICOM compatibility.

The following tables indicate the technical specifications of the CS-series-FP option:

1. Flat Panel Detector

1.1 Receptor Type	Amorphous Silicon
1.2 Conversion Screen	Cesium Iodide
1.3 Pixel Area – Active	19.8 cm X 19.8 cm
1.4 Pixel Matrix – Active	1024 X 1024
1.5 Pixel Pitch	194 µm
1.6 Limiting Resolution	2.58 lp/mm
1.7 MTF, X-ray	≥ 35% @ 1.30 lp/mm
1.8 Energy Range	40 – 150 kV
1.9 Fill Factor	70%
1.10 Dynamic Range	72 dB
1.11 Contrast Ratio	Large Area (120mm): < 0.8% Small Area (10mm): <7%
1.12 A/D Conversion	14-bits

2. Acquisition

2.1 Modes	Pulsed Fluoro, Spot, & Cine
2.2 Pulsed Fluoro Rates	3.75, 7.5, and 15 pps
2.3 Spot Rates	Single & 2 fps
2.4 Cine Rates	15 & 30 fps
2.5 Polarity	Positive & Negative
2.6 Edge Enhancement	5 level
2.7 Noise Reduction	6 level with motion correction
2.8 Last Image Hold	Yes
2.9 Fluoro Loops	Yes
2.10 Horizontal & Vertical Flip	Yes

3. Acquisition Workstation

3.1 Workstation Model	MX-200-OMI
3.2 Monitor, size	2 X 18.1 inch, Medical Grade, high contrast monochrome
3.3 Grey Levels	
3.4 Review (Fluoro Loops/Cine)	Forward, Reverse, Pause, and Speed
3.5 Window/Level Adjust	Yes
3.6 Annotation	Yes
3.7 Image Invert	Yes
3.8 Horizontal & Vertical Flip	Yes
3.9 Zoom & Roam	Yes (2X)
3.10 Image Storage	Minimum: 117,000 images
3.11 Networking Capabilities	Ethernet 10/100
3.12 DICOM Store	Yes
3.13 DICOM Print	Yes

3.14 DICOM Worklist Query	Yes
3.15 DICOM Send	Yes
3.16 Save to DVD/CD	With Embedded Viewer
3.17 Windows Print	Yes
3.18 Image Save	.JPEG & .AVI

4. Reference Monitor Identifiers [Review Station]

4.1 Patient Name	64 characters
4.2 Patient I.D.	64 characters
4.3 Date	8 characters (05/08/03)
4.4 Time	4 characters (13.:45)
4.5 Window/Level	0-4096
4.6 Hospital Name	64 characters
4.7 Physician Name	64 characters
4.8 Study I.D.	16 characters
4.9 Series/Image	3 characters/3 characters
4.10 Acquisition Mode	PF/DR/Cine
4.11 Image Orientation	Indicated by "R" orientation
4.12 Radiation	Radiation symbol during Live
I4.13 mage I.D.	e.g., LIH, Fluoro Loop, Spot, or Cine

5. Live Monitor Identifiers [Image Area]

5.1 Patient Name	64 characters
5.2 Patient I.D.	64 characters
5.3 Date	8 characters (05/08/03)
5.4 Time	4 characters (13.:45)
5.5 Window/Level	0-4096
5.6 Hospital Name	64 characters
5.7 Physician Name	64 characters
5.8 Study I.D.	16 characters
5.9 Series/Image	3 characters/3 characters
5.10 Image Orientation	Indicated by "R" orientation
5.11 Radiation Symbol	Radiation symbol during Live
5.12 Image I.D.	e.g., FL LIH, FL Loops, Spot Replay, or Cine Replay
5.13 Detector Status	Ready/Not Ready
5.14 Magnification Mode	Normal, MAG 1, MAG 2
5.15 Loop Replay	Play, Forward, Reverse, Speed, & Pause

GUI [Graphic User Interface on Reference Monitor]

Patient/Exam Entry	
5.16 Directory	Opens 'Patient Directory' screen
5.17 New	Opens 'Patient Data Entry' screen
5.18 Close	Closes active patient

Acquisition	
5.19 NR Hi / NR Lo	Selects Noise Reduction Level
5.20 L -> R	Live to Reference (monitor) transfer
5.21 FL @ 15	Right Click to invoke Fluoro Pulse Rate (15 f/s default, 7.5, & 3.75 f/s)
Note: Image Orientation available for Acquisition Mode (from Review)	
Review	
5.22 Edge (enhancement)	Increments from 0, 1, 2, 3, & 4
5.23 Win./Lev.	Window/Level adjustment
5.24 Split	Invokes 4 on 1 image display
5.25 Reference – Live	Toggles image between the Reference and Live monitors
5.26 Zoom	Up to 2X zoom with panning
5.27 Polarity	Video white on black or black on white
5.28 Collimate	Invokes electronic shutters
5.29 R (image orientation)	Toggles thru 1 of 4 positions
Additional Functions	
5.30 Send	Opens 'DICOM server node selection'
5.31 Print	Sends image to a Windows® compatible printer
5.32 Save	Saves current image to Hard Drive
5.33Text	Invokes the Annotation and Measurement function

- **System Components:** This option includes the solid-state x-ray imager (FPD) and image processor, along with associated mounting hardware and electrical/electronic components. These components are installed in lieu of the image intensifier/CCD camera and its image processor.

- **Materials:** The solid-state x-ray imager (FPD) construction and materials comply with UL2601-1, IEC60601-1, CSA 22.2 No. 601.1-M90, and is CE Marked. The imager is classified by Underwriters Laboratories.

- **Available Configurations:** The CS-series-FP is available in single plane and dual plane configurations.

Intended use:

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

Comparison with Predicate Devices:

- It is the opinion of Omega Medical Imaging, Inc. that the CS-*series*-FP is essentially equivalent to the Toshiba Infinix CCi/FPD system (K052884), the GE Innova 2000 (K993037), Philips Alura Xper FD10 F (K020055), and the Siemens Axiom Artis dFC (K021021).

DISCUSSION:

Review of the line items in the Comparison Table (Section 10.1) indicate that all items compared are either similar or the same as the predicate devices. The Flat-Panel Detector manufactured by Varian Medical Systems is utilized in similar FDA cleared fluoroscopic systems and has been in production for several years. All of the major operational features are either similar or the same as the predicate devices and therefore should offer essentially the same performance to the user as the predicate devices.

Non-Clinical Performance:

- Included in this report is detailed data comparing performance with the existing Omega Medical Imaging, Inc. CS-*series* systems utilizing an image-intensifier/CCD based image acquisition system. Also included is detailed specifications and performance of the Varian PaxScan 2020 flat-panel detector.

Safety information:

- The Omega CS-*series*-FP (SSXI) 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*-FP 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, IEC 60601-2-32, and IEC 60601-2-43.

CONCLUSION:

The Omega CS-*series*-FP (SSXI) 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*-FP (SSXI) systems with the flat-panel detector option to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

JUL 30 2012

Re: K100102
Trade/Device Name: CS-series-FP Fluoroscopy System with optional Solid State X-ray Imaging Device (Flat-Panel Detector)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, and MQB
Dated: July 23, 2010
Received: July 29, 2010

Dear Mr. Princehorn:

This letter corrects our substantially equivalent letter of August 31, 2010.
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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K100102

510(k) Number (if known): _____

Device Name: CS-*series*-FP (SSXI)

AUG 31 2010

Indications for Use:

The Omega Medical Imaging, Inc. CS-*series*-FP (SSXI) systems are intended for use in radiographic/fluoroscopic application including cardiac, vascular, general radiographic/fluoroscopic diagnostic, and interventional x-ray imaging.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100102