K093572

510(k) SUMMARY

FEB - 3 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:	16 November 2009
Device (trade) name:	Automatic Beam-limiting Device Model R650 QDASM
Common/usual name:	Automatic Radiographic/fluoroscopic Collimator
Classification name:	Diagnostic X-Ray Beam-Limiting Device (21 CFR 892.1610) Class II (Procode: 90 IZW)

Predicate device:

- Dunlee automatic "FORMAT A" collimator manufactured by Philips Medical Systems legally marketed under number K031597.
- Omega Model R605 FACS collimators manufactured by RALCO S.R.L legally marketed under number K050092

Device description:
The Omega R 650 QDASM is an automatic beam limiting device designed for use in diagnostic radiographic/fluoroscopic applications. It includes square field shutters, spectral filters, and an additional lung filter for cardiac application. This device is substantially equivalent to the predicate devices with respect to technological characteristics.

Intended use:

- The Omega R650 QDASM automatic beam limiting device is intended for use in diagnostic radiographic/fluoroscopic applications.

Safety information:

- The Omega R650 QDASM collimator will comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31, and 21 CFR 1020.32.
- The Omega R650 QDASM collimator will comply with the international safety standards IEC 60601-1, IEC 60101-1-2, and IEC 60601-1-3.
- The Omega R650 QDASM will comply with CE Marking requirements.
- The Omega R650 QDASM will comply with UL 60601-1 and CAN/USA C22.2 No.601.1-M90

Conclusion:
The Omega R650 QDASM collimator does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Omega considers the R650 QDASM collimator 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

FEB - 3 2010

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

Re: K093572
Trade/Device Name: R650 QDASM Beam Limiting Device
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam-limiting device
Regulatory Class: II
Product Code: IZW
Dated: November 16, 2009
Received: November 18, 2009

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 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,

Donald J. St.Pierre
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 Form

510(k) Number (if known): K093572

Device Name: R650 QDASM Beam Limiting Device

Indications for Use:

The Omega R650 QDASM automatic beam limiting device is intended for use in X-ray diagnostic radiographic/fluoroscopic applications.

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 In Vitro Diagnostic Devices (OIVD)

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

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