FEB 2 1999

K990053

OMEGA MEDICAL IMAGING, INC. B-400

January 6, 1999

510 (k) Summary

Submitter: Omega Medical Imaging, Inc., 675 Hickman Circle, Sanford, FL 32771
Douglas M. Coon, President.

Device Name: B-400 Isocentric Ceiling Mounted C-Positioner.

Classification Name: System, Fluoroscopic, Image Intensified, All Types.

Common/Usual Name: C-Arm

Substantially Equivalent Devices: Fisher's ***PEGASUS*** Ceiling Mounted Cardiac Positioner, Fisher's ***ARIEL*** Ceiling Mounted C-Arm, Fisher's ***CPS*** Ceiling Mounted Imaging System, Philip's ***INTEGRIS HM 3000*** and Omega B-350 Ceiling Mounted Positioner.

Description: The B-400 Ceiling Mounted C-Positioner is a device intended to hold an X-Ray tube and an image intensifier 180° apart in a "C" configuration for the purpose of performing general purpose diagnostic fluoroscopic procedures.

The C-Positioner allows variable positioning of the X-Ray tube/Image Intensifier from +145 degrees Left Anterior Oblique (LAO) to 55 degrees Left Posterior Oblique (LPO). The device will maintain isocenter throughout its full range of motorized movement. The entire assembly is mounted to a set of ceiling rails.

Intended Use: To support the Diagnostic Source Assembly & Image Receptor used in performing general-purpose diagnostic fluoroscopic procedures.

Summary of Technological Characteristics: The B-400 Ceiling Mounted C-Positioner has the same technological characteristics as the predicate devices. The B-400 and the predicate devices all have the same intended use: to support the X-Ray tube (Diagnostic Source Assembly) and the Image Intensifier (Image Receptor) directly opposite each other with some variation in the distance from the X-Ray tube to the Image Receptor (SID), for diagnostic fluoroscopic procedures. The only differences in the devices are market driven variables such as the SID, arc rotation for different procedures, and the ability to rotate about the ceiling axis. The above devices are essentially all ceiling suspended C-Arms with some variations, depending on user preference. The Omega B-400 Ceiling Mounted C-Positioner (C-Arm) is substantially equivalent to the predicate devices as well as any number of other Ceiling Mounted C-Arms that have been legally marketed in the U.S. for many years.

SUBSTANTIAL EQUIVALENCE COMPARISON

Device Model:	Omega B400	Omega B350	Fisher Pegasus	Fisher Ariel	Philips Integras HM 3000
510(k):	Submitted Herein	K970947	K915592	K880527	K923813
Classification:	90JAA	90JAA	90JAA	90JAA	90JAA
Description:	Ceiling Mounted 'C' Positioner	Ceiling Mounted 'C' Positioner	Ceiling Mounted Cardiac Positioner	Ceiling Mounted Fluoroscopy C-Arm	Ceiling Mounted C-Arm Portion
Intended Use:	'C'-Arm to support X-Ray Diagnostic Source Assembly & Image Receptor for Fluoroscopy	'C'-Arm to support X-Ray Diagnostic Source Assembly & Image Receptor for Fluoroscopy	'C'-Arm to support X-Ray Diagnostic Source Assembly & Image Receptor for Fluoroscopy	'C'-Arm to support X-Ray Diagnostic Source Assembly & Image Receptor for Fluoroscopy	'C'-Arm to support X-Ray Diagnostic Source Assembly & Image Receptor for Fluoroscopy
Source to Image Distance (SID):	Variable 46" to 56"	Variable 32"to 42"	Variable 34" to 50"	Not available	Variable 86.5 to 116.6 cm
Rotation about Vertical Axis:	+/- 180°	Fixed at lateral center	+45°/-90°	+90°/-90°	+90°/-90°
Arc Rotation:	+145°/-55°	+60°/-30° (30° LAO to 120° LPO)	+30°/-90°	+45°/-45°	+70°/ 90° LAO/RAO
C-Arm Radius (Throat):	36"	43"	46½"	Not available	36"
C-Arm Width O.D. Dimension:	78"	89"	91"	Not available	Not available

DISCUSSION: All of the devices listed above have the same intended use: to support the X-Ray tube (Diagnostic Source Assembly) and the Image Intensifier (Image Receptor) directly opposite each other with some variation in the distance from the X-Ray tube to the Image Receptor (SID), for diagnostic fluoroscopic procedures. The only differences in the above devices are market driven variables such as the SID, arc rotation for different procedures, and the ability to rotate about the ceiling axis. The above devices are essentially all ceiling suspended C-Arms with some variations depending on user preference. The Omega B-400 Ceiling Mounted C-Positioner (C-Arm) has the same intended use & technological characteristics as the above listed devices as well as any number of other Ceiling Mounted C-Arms that have been legally marketed in the U.S. for many years.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Douglas Coon
President & CEO
Omega Medical Imaging Incorporated
675 Hickman Circle
Sanford, FL 32771

Re: K990055
B-400 Ceiling Mounted Positioner
Dated: January 6, 1999
Received: January 7, 1999
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. Coon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990555

Device Name: Model B-400 C-Arm (C-Positioner)

Indications For Use:

Device Intended Use

This device is intended to support the X-Ray Diagnostic Source Assembly and the Image Receptor. It is not designed nor intended to be used in any General Purpose X-Ray System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990555

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)