DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Mr. Richard Westrich
VP Product Development and
Regulatory Affairs
Ziehm Imaging, Inc.
4181 Latham Street
RIVERSIDE CA 92501

Re: K051064
Trade/Device Name: ZIEHM QUANTUM (Mobile x-ray system)
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: April 26, 2005
Received: April 26, 2005

Dear Mr. Westrich:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indication of Use Statement

Applicant: Ziehm Imaging, Inc.
4181 Latham Street
Riverside CA. 92501

510(k) Number: K051064

Device Name: ZIEHM QUANTUM
(Mobile x-ray system)

Indications for Use:

The ZIEHM QUANTUM series Mobile C-Arm is intended for use in both Radiographic and Fluoroscopic exams, including a wide variety of surgical intervention or guidance procedures requiring X-ray imaging - both inside and outside the operating room. These include Cerebral, Thoracic, Vascular surgery; Abdominal, Orthopaedic, Peripheral, special Vascular-Flow Procedures, Dilatation, Embolization, Stent Placement, Urological Procedures as well as Neuro-Vascular, and other related fluoroscopic examinations requiring interventional procedures.

The ZIEHM QUANTUM Mobile C-arms are also suitable as a back up for fixed-based X-ray Vascular and Intervention Procedures.

Radiographic film examinations can be made with an accessory cassette device attached to the Image Intensifier.

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051064