DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 4 2006

Mr. J. Damon Kirk
President
WFR/Aquaplast Corporation, Qfix Systems
30 Lawlins Park
WYCKOFF NJ 07481

Re: K060671
Trade/Device Name: kVue IGRT Treatment Table Top
Regulation Number: 21 CFR 892.5770
Regulation Name: Powered radiation therapy patient support assembly
Regulatory Class: II
Product Code: JAI
Dated: March 9, 2006
Received: March 14, 2006

Dear Mr. Kirk:

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/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

2.0

PREMARKET NOTIFICATION
INDICATION FOR USE

The kVue IGRT Treatment Table Top, inserts, and accessories are designed to position and support patients undergoing radiation therapy. The kVue Treatment Table Top is designed to replace an original equipment manufacturer's stock table top. The Qfix kVue Patient Positioning Table Top and inserts are made using sliding beams and advanced fiber composites that contain no metal parts in the treatment area, thus allowing the devices to be used in various diagnostic and treatment modalities without fear of interference caused by metal parts. In particular these devices are designed for optimal performance when used with on board imaging and cone beam CT while simultaneously reducing beam attenuation for treatments that pass through the couch. The kVue inserts include the Cantilever Board insert, the Quest Breast Board insert, the prone breast board insert, the Qfix Pelvis/Belly Board insert, the Box Grid insert, the Solid Panel insert, the Center Spine insert, the DoseMax insert, and the removable tip extension. kVue accessories include the device adapter bar, the VacuFix Bags, the removable clamp rail, and the removable tip extension hardware.

Signature

J. Damon Kirk

03/09/2006

Premarket Notification 510(k) Number K 060671

Prescription Use ✓

David G. Legorreta

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060671