DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 16 2005

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Gary Lamoureux
President/CEO
World Wide Medical Technologies
Oxford, CT 06478

Re: Docket No. 2005P-0084

Dear Mr. Lamoureux:

This is an interim response to your petition filed by the Food and Drug Administration (FDA) on February 23, 2005. In your petition, you urge FDA to safeguard the public from brachytherapy kits that use non-absorbable bone wax or reformulated "faux bone wax" needle plugs to treat prostate cancer. In your petition, you stated that overwhelming scientific data indicates that brachytherapy kits that use bone wax or reformulated faux bone wax as needle plugs to treat prostate cancer present an unreasonable and substantial risk of illness or injury. You also state that you believe that companies that manufacture the radioactive seeds that are used in brachytherapy kits, and the subcontractors who assemble these kits for them, have recently begun to market these kits to hospitals and physicians without giving appropriate consideration to the potential dangers identified in the scientific literature.

You specifically request that FDA:

1. Ban the use of commercial brachytherapy kits in accordance with section 516 (a) (1) of the Federal Food, Drug and Cosmetic Act;

2. At a minimum, require manufacturers of brachytherapy kits to obtain premarket approval (PMA) prior to commercial distribution; and

3. Rescind existing 510 (k) substantial equivalence clearance for brachytherapy kits that use bone wax or reformulated bone wax needle plugs, and remove from the market brachytherapy kits currently marketed in the absence of 510 (k) clearance or PMA approval.

Your petition raises scientific and legal issues that require further review by the agency. We are still considering these issues and are unable to provide a final response at this time. We expect to issue a final response in the near future.

2005P.0084

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If you have any questions about this interim response, please contact Rosa M. Gilmore of our Regulations Staff at (301) 827-2970.

Sincerely Yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director
Center for Devices and Radiological Health