Nucletron

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Ray Manley
Radiological Health Program
Maryland Department of the Environment
1800 Washington Boulevard, Suite 750
Baltimore, MD 21230

Our reference:	Your reference:	Date:
Cor 103106		October 31, 2006

Dear Mr. Manley:

In May, 2006 Nucletron submitted a sealed source and device (SS&D) application for a new afterloader at which time the cover letter for the SS&D application requested a "***timely review***" of the application because 510(k) clearance was expected in July of 2007. Upon FDA clearance, Nucletron planned to commercialize the microSelectrron HDR (V3) afterloader. FDA clearance was issued on August 17, 2006. The concerning afterloader is almost identical to Nucletron's Model 105.999 (aka V2), PDR, and OncoSelect HDR-3 afterloaders currently in distribution. The modifications to the concerning afterloader are duly noted in the application. Issuance of the SS&D for the microSelectron HDR (V3) is becoming urgent as 2007 approaches. The microSelectron V3 is intended to replace Nucletron's afterloaders currently manufactured. Therefore in 2007, the Model 105.999, PDR, and OncoSelect HDR-3 will not be manufactured.

Nucletron hereby requests the review of the SS&D application for the Nucletron microSelectron V3 be expedited so that cancer treatment facilities purchasing afterloaders from Nucletron Corporation can license these devices. An indication of the remaining review time needed by Maryland Department of the Environment for the microSelectron HDR V3 is requested in an effort to better manage expectations. Please reply to the undersigned at 443-545-2196 or lisa.dimmick@us.nucletron.com.

Kind Regards,

Lisa Dimmick
Director Regulatory Affairs, RSO