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510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitter's Name:** Nordion International Inc.
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Date Summary Prepared: August 27, 1996
2. **Common or Usual Name:** Blood irradiator.
Proprietary Name: Gammacell 3000 ELAN, Version 1.0
Gammacell 1000 ELITE, Version 1.0
3. **Legally Marketed Device:** Gammacell 3000 Elan, Version 2.09
Gammacell 1000 Elite, Version 2.09
File Number of Last 510(k): K952291

4. Product description:

The modified Gammacell E- series Blood Irradiator models, the 1000 Elite and the 3000 Elan use the new software version 1.0 control system. With the exception of the modified control system, the 1000 Elite and 3000 Elan are identical to previously cleared models.

The basic operation of an irradiator involves placing of the blood product into the beaker, loading the beaker into the Gammacell, closing the safety door and pressing the "start" button. Upon start of the cycle, the unit moves the beaker to irradiate position and rotates the blood product continuously at a uniform speed to provide a consistent dose of irradiation. Concurrently, the timer begins to count down (irradiation time is pre-programmed by the site supervisor) from the set time and when the time reaches zero, the sample returns to unload position and the audible alarm sounds. If the cycle is completed as pre-programmed the message "cycle completed OK:" is displayed. Any problems in the irradiation cycle will be displayed specifically and clearly.

5. Intended Use:

The **intended use** of the modified Gammacell with **version 1.0** control system remains unchanged. Both the improved and the predicate device effectively irradiate blood and blood components to inactivate leukocytes and lymphocytes.

6. Technological Comparison:

The basic function of the Gammacell 1000 Elite and Gammacell 3000 Elan with the modified control system has not been changed from the predicate Gammacell 1000E and 3000E. However, some technological changes are being made to the control system primarily to make the unit more user friendly. Precisely, the operator display panel has been simplified, and the information and error messages displayed on the panel have been written so that they can be readily understood by the operator. The access to the machine is effectively controlled through enhanced security and access controls. In addition, the modified unit is proven to withstand any electromagnetic interference that may affect the function of the control system.

7. Safety and Efficacy:

Safety:

The **safety** of the Gammacell is equivalent or better than the predicate device. The irradiation source and the radioactivity of the caesium-137 source(s) remains unchanged.

In terms of electrical safety, all units are designed to comply with applicable standards of the Canadian Standards Association and are certified as such by the CSA. In addition, the modified units are tested and demonstrated for compliance with Electromagnetic Compatibility (EMC).

Efficacy:

The performance of the device was tested against a set of functional specifications in an environment which simulated, as much as possible, the actual operating environment. The functional requirements included security and safety functions, operational features, timing and counting functions, ancillary equipment such as independent Backup Timer and Beaker Rotation Sensing System, operator interface etc. Validation testing results provide documented evidence that the equipment design tested, adequately meets the functional requirements and the device is as safe and effective as the predicate device.

8. Conclusion:

Although some new features have been added to the new control system, mainly for the purpose of operator conveniences, these new features in no way compromise the intended use, safety or effectiveness of the device. The modified device models, with Version 1.0, are substantially equivalent to the 510(k) cleared models with Version 2.09