BK000008

A. Summary.

It has been demonstrated that transfusion associated graft-versus host disease (TA-GVHD) can result from the transfusion of non-irradiated blood to immunodeficient patients. TA-GVHD can effectively be prevented in susceptible individuals by the irradiation of blood components prior to transfusion. Although rare, TA-GVHD carries a high mortality rate, with death occurring in more than 90% of cases. Therefore blood irradiation has become standard practice before transfusion to certain groups of immunodeficient patients.

The RadTag label has been developed to provide unequivocal verification that blood units have been irradiated to the required dose.

The label is attached to the bag of blood before it is placed in the irradiator. The sensitive portion of this device is clear at this time. After irradiation , the clear dot changes to blue, the shade of blue being an approximate indication of the amount of radiation dose delivered.

Please note however, that this device is meant as a process indicator and not as a radiation dosimeter. The color change is permanent and immediate and does not require any further processing or development.

The amount of color change has been optimized to give a clear indication that the product has been processed at the levels of irradiation currently used in the processing of blood. A typical blood processing unit will use 2500 Rads (25Gy) as a specified dose, delivered to the central portion of the irradiation container, and 1500 Rads (15Gy) is the minimum dose at any other point. This is in compliance with Directive D96-009, Irradiation of Blood Components.

B. Submitter:

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C. Contact:

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D. Date of Application:

February 1, 2000

E. Trade Name:

RadTag

F. Common Name:

Radiation Process Indicator

G Substantially Equivalent to:

RadTag: BK960068
RadSure: BK910018, BK920035

H. Description.

The RadTag Label consists of three layers:

Layer 1.

A base label on which is printed textual information. This layer may also have printed a reference color or colors, to which the sensitive portion of the device can be compared in order to provide a semi-quantitative estimate of the radiation dose delivered. This base layer is the part of the device which is attached directly to the blood bag. The adhesive which is in contact with the blood bag is subject to safety issues, and complies with Title 21, Part 175.105 of the Code of Federal Regulations.

Layer 2.

A radiation sensitive portion, which is a material such as a paper or plastic film of approximately ¼" diameter, which is coated with a sensitive chemical which changes from clear to blue when irradiated. This layer is attached to the base label by the third layer.

Layer 3.

A clear Mylar protective film in the form of a disk approximately ¾" diameter, which is placed over the second layer in order to protect the sensitive portion from ultraviolet exposure and moisture, which can also cause a color change to the unprotected sensitive layer.

The basic construction of the device in this current application is exactly the same as for the previously approved product BK960068.

I. **Indications for Use.**

Each RadTag label is a small label to indicate if a blood unit has been irradiated. The originally approved device was designed for irradiation systems using gamma ray emissions of Cs-137, which are the predominant systems. This application is for a device to be used with recently produced x-ray irradiation systems.