APR - 9 1996

K940663

APPENDIX IV

SUMMARY OF SAFETY AND EFFECTIVENESS

Peacock Plan

K940663

Pursuant to Section 513(i) of the Federal Food, Drug, and Cosmetic Act

I. General Information

Classification Name: Radiation Therapy Simulation System

Common/Usual Name: Radiation therapy treatment planning computer program

Trade/Proprietary Name: Peacock Plan

Applicant's Name and Address:

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II. Name of predicate device(s):

1.Small Systems Group: Prowess 2000, K884261/A/B
2.GE Target Series 2, K896353
3.University of Michigan/Scanditronix: Scandiplan K903403

III. Classification:

Radiation Therapy Simulation Systems were reviewed by the Radiological Devices Classification Panel and placed in Class II (21 CFR 892.5840).

IV. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description:

The NOMOS Peacock Plan is a radiation treatment planning package designed to allow medical physicists, dosimetrists and radiation oncologists to create conformal treatment plans using photon (x-ray) external beam radiation therapy. The treatment plans generated by Peacock are based upon treatment machine specific data and are intended to provide a guide to delivering exrernal beam radiation therapy which conforms to the target volume defined by the radiation oncologist.

Peacock Plan has been designed to generate plans for the implementation of 3-D Conformal Radiation Therapy (3-D-CRT) in a manner similar to the predicate devices listed above (Small Systems Group: Prowess 2000, K884261/A/B; GE Target Series 2, K896353; University of Michigan/Scanditronix: Scandiplan K903403). The basis for 3-D-CRT and its implementation is the mirror image of computerized tomography (General Electric K841997, Siemens K910859/A). The Peacock Plan and CT both use variations on computer implementations of filtered backprojection algorithms. In CT, a spatially-uniform-radiation exposure is delivered to the patient and the spatially non-uniform attenuation of the exit beam is measured. Peacock Plan creates treatment simulations based upon user annotated CT information. This information describes the desired shape of the isodose distribution and location of the desired dose. Peacock Plan then defines the beam intensities and shapes to produce this desired dose distribution at the target site. With Peacock Plan, a multileaf collimator, partial-attenuation block or other beam-blocking mechanisms may be employed to generate a spatially, non uniform beam which, when directed at the tumor, will form a spatially- uniform dose around the target volume.

The current version of Peacock Plan is valid for use only with external beam photon therapy; calculations for electrons and intracavitary sources (Brachytherapy) are <u>not</u> supported.

VI. Summary of Substantial Equivalence:

<u>Indications</u>: The indications for the NOMOS Peacock Plan are the same as those for the predicate devices with external beam radiation: Present a graphical display of the resultant dose distribution around a target which is based upon the size, shape and position of the radiation treatment fields.

<u>Design</u>: The design of the NOMOS Peacock Plan is similar to those used in the predicate devices.

<u>Materials</u>: The materials used in the NOMOS Peacock Plan is similar to that of the predicate devices.

<u>Manufacturing</u>: The manufacturing processes used in the NOMOS Peacock Plan are similar to those used in the manufacture of predicate devices.

Specifications: The specifications of the NOMOS Peacock Plan are similar to those of the predicate devices.

Conclusions: The indications, design, materials, manufacturing, and specifications of Peacock Plan do not raise any new issues relating to safety and effectiveness.

NOMOS thus considers the Peacock Plan to be substantially equivalent to the predicate devices.