

Premarket Notification - Peacock™ System

NOV 18 1996

K96 3258

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act
August 19, 1996

1. General Provisions

Trade/Proprietary Name

NOMOS PEACOCK System consisting of:

CORVUS (cleared as Peacock™ Plan; K940663)
MIMiC™ (K940412)

Common/Usual Name

Integrated radiation therapy treatment planning and delivery system

Radiation therapy treatment planning system (CORVUS)

Linear accelerator mounted treatment delivery system (MIMiC)

Applicant Name and Address

NOMOS Corporation
2591 Wexford Bayne Road
Sewickley, PA 15143

2. Names of Predicate Devices¹

Integrated PEACOCK Treatment Planning and Delivery System:

Varian Varisource HDR Afterloader with integrated planning system (K852842)
GE Target Planning System (K896353) & Arc Therapy (K802809)

These systems were marketed prior to and/or following enactment of the Medical Device Amendments on May 28, 1976.

3. Classification

Radiation therapy simulation systems were reviewed by the Radiological Devices Classification Panel and placed in Class II (21 CFR 892.5050); an accessory to a medical charged particle radiation therapy system.

MIMiC, a radiation therapy beam-shaping block, is classified as class II according to 21 CFR 892.5710; a radiation therapy beam shaping block.

These devices are reviewed by the Radiological Devices Panel of the Division of Reproductive, Abdominal, ENT, and Radiological Devices.

4. Performance Standards

Not applicable.

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5. Intended Use and Device Description

This device is intended to be used as an integrated system for the planning and delivery of dynamic conformal radiation therapy to produce a radiation field which is modulated to conform to the projected tumor volume plus margins by means of a dynamic (moving) multileaf collimator, while simultaneously moving the accelerator gantry.

6. Summary of Substantial Equivalence

The Peacock System is similar in design, construction, materials, intended use and performance characteristics to the predicate treatment planning systems and multileaf collimators. Physics and clinical testing has demonstrated that the Peacock System performs as intended. No new issues of safety or effectiveness are introduced by using this device.