K092534

SECTION 5 – 510(k) SUMMARY

DEC - 7 2009

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Date Prepared

July 29, 2009

Trade Name

ALATUS Vaginal Balloon Packing System

Regulation Name(s)

Medical charged-particle radiation therapy system (primary)
Obstetric-gynecologic general manual instrument (secondary)

Regulation Number(s)

892.5050 (primary)
884.4520 (secondary)

Classification Name(s)

System, planning, radiation therapy treatment (primary)
Retractor, vaginal (secondary)

Product Code(s)

MUJ (primary)
HDL (secondary)

Classification Panel

Radiology (primary)
Obstetrics/Gynecology (secondary)

Regulatory Class

Class II

Device Description

The **ALATUS Vaginal Balloon Packing System** is designed as an immobilizer to assist in positioning and displacing the vaginal wall in a more predictable and reproducible location during computed tomography (CT) exams and radiation treatment (RT) therapy. The proposed device is a latex free balloon made from Polyurethane consisting of the following components:

1. Balloon
2. Catheter tubing
3. Connector
4. Flex tubing
5. 1-way stopcock, 90° turn handle

Intended Use

The **ALATUS Vaginal Balloon Packing System** is a single use, non-sterile, disposable, flexible, inflatable, non-powered positioning device, intended to be used on a daily treatment basis for the temporary positioning of the vaginal wall and adjacent structural anatomies. The purpose of the device is to displace and stabilize the vaginal wall during computed tomography (CT) exam, x-ray, or radiation treatment (RT) therapy. The placement of the balloon requires a physician or physician directed healthcare professional, and it is performed as a separate procedure outside of the standard (CT) exam and (RT) treatment. This device is not intended to be inserted into the uterine cavity.

Predicate Device(s)

1. Mick Radio-Nuclear Instruments, Inc. – *Vaginal Applicator Shielded* (K001544)
2. Sterilis, Inc. – *Vaginal Port Inflatable Speculum* (K002912)

Safety and Effectiveness

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the **ALATUS Vaginal Balloon Packing System** and the predicate devices listed do not raise any questions regarding its safety and effectiveness. The subject device, as designed and manufactured, is as safe and effective as the predicate devices for its intended application; that is, as a temporary vaginal wall positioning device, and therefore is determined to be substantially equivalent to the referenced predicate devices in the context of that application.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Radiadyne
% Mr. Stuart R. Goldman
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DEC – 7 2009

Re: K092534
Trade/Device Name: ALATUS Vaginal Balloon Packing System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ and IYE
Dated: November 20, 2009
Received: November 23, 2009

Dear Mr. Goldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092534

Device Name

ALATUS Vaginal Balloon Packing System

Indications for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K092534