K123941

APR 3 0 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is furnished in accordance with requirements detailed in 21 CFR 807.92.

1.
The assigned 510(k) number is K-TBD

Submitter's Identification:
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Date of submission 14 December 2012

2.
Device name:

1. Vaginal Cylinders

Proprietary name: Kobold Sure-guide Vaginal Cylinder Set™

2. Stump Cylinders

Proprietary name: Kobold Sure-guide Stump Vaginal Cylinder Set™

3. Miami Cylinders

Proprietary name: Kobold Sure-guide Miami Cylinder Set™

A. Regulation Section 892.5700
B. Classification: Class II
C. Product Code: JAQ
D. Panel: Radiology

3.
Intended Use:

Vaginal

The CT/MRI Compatible Sure-guide Vaginal Cylinder Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.

Stump

The CT/MRI Compatible Sure-guide Stump Vaginal Cylinder Set is indicated for use in any patient case where High dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.

Miami

The CT/MRI Compatible Miami HDR Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the cervix, vagina, and uterus is acceptable by up-to-date clinical and practice guidelines.

4.
Device Description:

1. Vaginal

The CT/MRI compatible Sure-guide Vaginal Cylinder Set design is based on conventional cylindrical HDR delivery systems with a click fit connector interface. This applicator is particularly useful in providing an HDR radiation as definitive treatment, adjuvant treatment, or as a treatment boost to the vaginal walls with or without external beam radiation therapy. The set consists of a precision manufactured Sure-guide cylinders of varied diameters for optimal radiation treatment delivery and anatomical customization.

2. Stump

The CT/MRI Compatible Sure-guide Stump Vaginal Cylinder Set design is based on conventional cylindrical HDR delivery systems with a click fit connector interface. This applicator is particularly useful in providing an HDR radiation as definitive treatment, adjuvant treatment, or as a treatment boost to the vaginal walls with or without external beam radiation therapy. The set consists of a precision-manufactured

Sure-guide Stump Cylinders of varied diameters for optimal radiation treatment delivery and anatomical customization.

3. Miami

The CT/MRI Compatible Sure-guide Miami HDR applicator Set is designed according to the conventional modified Miami applicator with a click fit connector interface. This applicator is particularly useful when the vaginal vault space is limited or narrow due to tumor, restricted anatomy, or fibrosis. It can also be useful to treat tumors that extend from the uterus or cervix down onto the vaginal wall. The set consists of a precision manufactured intrauterine tandems and a full set of variable diameter Miami cylinders (all components are designed to allow for customization of the treated geometry). The distance that the tandem is inserted can be customized for each case. Four differing tandems are provided: one straight, one slight curvature, one medium curvature, and one maximal curvature. These allow for maximal accommodation of the uterine flexure.

5.
Substantial Equivalence Information:

Information presented supports substantial equivalence of the Kobold Sure-guide™ Vaginal, Stump and Miami versions of the cylinder set to the predicate device. Each of the proposed versions of the device has the same indications for use, has similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same sterilization procedures. Please see predicate device description in **Appendix C**.

A. Predicate device names: Intracavity BrachyTherapy Applicators
B. Predicate device K numbers: K-033371
C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	KOBOLD LLC	KOBOLD LLC	VARIAN, INC.®
K-Number	TBD	TBD	TBD	K-033371
Device Description	Cylinder Set, Vaginal	Cylinder Set, Stump Vaginal	Cylinder Set, Miami	Cylinder Set, Vaginal, Stump, Cervical (Miami)

Kobold Cylinders

Indications for Use	The CT/MRI Compatible Sure-guide Vaginal Cylinder Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.	The CT/MRI Compatible Sure-guide Stump Vaginal Cylinder Set is indicated for use in any patient case where High dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.	The CT/MRI Compatible Miami HDR Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the cervix, vagina, and uterus is acceptable by up-to-date clinical and practice guidelines.	Vaginal Applicator Set is developed for intracavity brachytherapy to treat cancer of the vagina or rectum. The maximum implantation time for this applicator is 30 days.
Afterloader Compatibility	GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.
Materials	Titanium, Ultem®, Silicone, High Temperature Vinyl	Titanium, Ultem®, Silicone, High Temperature Vinyl	Titanium, Ultem®, Silicone, High Temperature Vinyl, Stainless Steel	PPSU, PVDF, Acetal, Stainless Steel, PEEK
Packing	Tray	Tray	Tray	Not Documented
Sterility	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions,	Steam 18 min at 273°F (134°C), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273°F (134°C), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273°F (134°C), 44psi (3 bar) Dry 15 min.	Steam Sterilizable
Biocompatibility	Documented	Documented	Documented	Not Documented
Anatomical Sites	vagina	vagina	cervix, vagina, and uterus	cervix, vagina, and uterus
Environmental Compatibility	CT/MRI Compatible	CT/MRI Compatible	CT/MRI Compatible	CT/MRI Compatible

6.

Test Principle, Performance Characteristics:

FDA has not established special controls or performance standards for this device.

7.

Bench Top Testing

Extensive testing in accordance with known standards is documented by the manufacturer. The standards are specifications for the materials used in surgical implant applications, predicate brachytherapy devices and manufacturer's acceptance procedures. Mechanical testing of the finished devices is additionally described in **Appendix A**. Cleaning/Sterilization validation test results are also included.

8.

Conclusions

All versions of Kobold's Sure-guide Cylinder Set™ are similar in intended use and technological characteristics to predicate devices reviewed. Each version of the device is similar with respect to indications for use and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Contraindications: As per clinical guidelines and standard clinical practice.

Warnings and Precautions: The precautions are provided in the device labeling for the Kobold Sure-guide Vaginal Cylinder Set™ , Kobold Sure-guide Stump Vaginal Cylinder Set™ and Kobold Sure-guide Miami Cylinder Set™. There is no warning associated with this type of device.

9.

Summary

Description	Comparison with Predicate Device
Biocompatibility	Safe as Predicate Device
Performance Characteristics	Substantially equivalent
Intended Use	Substantially equivalent
Performance Tests	Not Required

Each version of the device, Kobold Sure-guide Vaginal Cylinder Set™ , Kobold Sure-guide Stump Vaginal Cylinder Set™ and Kobold Sure-guide Miami Cylinder Set™, based on the information submitted in this 510(k) application has been demonstrated to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 30, 2013

Kobold, LLC
% Ms. Christina Bernstein
Regulatory Director
2670 Leavenworth Street
San Francisco, CA 94133

Re: K123941
Trade/Device Name: Kobold Sure-guide Vaginal Cylinder Set™
Kobold Sure-guide Stump Vaginal Cylinder Set™
Kobold Sure-guide Miami Cylinder Set™
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: March 13, 2013
Received: March 18, 2013

Dear Ms. Bernstein:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Michael D. O'Hara for

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123941

1. Device Name: Kobold Sure-guide Vaginal Cylinder Set™

Indications for Use:

The CT/MRI Compatible Sure-guide Vaginal Cylinder Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.

2. Device Name: Kobold Sure-guide Stump Vaginal Cylinder Set™

Indications for Use:

The CT/MRI Compatible Sure-guide Stump Vaginal Cylinder Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the vagina is acceptable by up-to-date clinical and practice guidelines.

3. Device Name: Kobold Sure-guide Miami Cylinder Set™

Indications for Use:

The CT/MRI Compatible Miami HDR Set is indicated for use in any patient case where High Dose Rate (HDR) radiation treatment of the cervix, vagina, and uterus is acceptable by up-to-date clinical and practice guidelines.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____**K123941**_____