DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2017

Kobold, LLC
% Ms. Christina Bernstein
Engineer
BB Medical Surgical
1736 Stockton Street, Studio 9
SAN FRANCISCO CA 94133

Re: K160610
Trade/Device Name: Kobold® Fletcher-model Tandem and Ovoid Applicator Set, Kobold® Henschke-model Tandem and Ovoid Applicator Set, Kobold® Vaginal Cylinder Applicator Set, Kobold® Miami Cylinder Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: January 17, 2017
Received: January 18, 2017

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

The complete Indications for Use form (FDA 3881) for the devices is reproduced here.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160610

Device Name
Kobold® Fletcher-model Tandem and Ovoid Applicator Set, Kobold® Henschke-model Tandem and Ovoid Applicator Set, Kobold® Vaginal Cylinder Applicator Set, Kobold® Miami Cylinder Applicator Set

Indications for Use *(Describe)*

The CT Compatible / MR Unsafe HDR Kobold® Fletcher-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Fletcher type applicator is accepted by up-to-date clinical guidelines. The Kobold® Fletcher-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Henschke-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Henschke type applicator is accepted by up-to-date clinical guidelines. The Kobold® Henschke-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Vaginal Cylinder Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the vagina is accepted by up-to-date clinical guidelines. The Kobold® Vaginal Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Miami Cylinder Applicator Set is indicated for use in any patient case where high dose rate (HDR) radiation treatment of the cervix, vagina, and uterus with a Miami type applicator is acceptable by up-to-date clinical guidelines. The Kobold® Miami Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Kobold® Fletcher-model Tandem and Ovoid Applicator Set, Kobold® Henschke-model Tandem and Ovoid Applicator Set, Kobold® Vaginal Cylinder Applicator Set, Kobold® Miami Cylinder Applicator Set

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

1.
The assigned submission number is K-160610

Submitter's Identification:

Deanna Hughes
Kobold, LLC
PO Box 1994
Veradale, WA 99037

Correspondence:

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Veradale, WA 99037
Tel: 818.321.0116
Email: Deanna.Hughes@koboldmedical.com

Date of submission: January 17, 2017

2.
Device names:

Fletcher Type Applicator Set
Proprietary name: Kobold® Fletcher-model Tandem and Ovoid Applicator Set

Henschke Type Applicator Set
Proprietary name: Kobold® Henschke-model Tandem and Ovoid Applicator Set

Vaginal Cylinder Set
Proprietary name: Kobold® Vaginal Cylinder Applicator Set

Miami Cylinder Set
Proprietary name: Kobold® Miami Cylinder Applicator Set

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

3.
Intended Use:

The CT Compatible / MR Unsafe HDR Kobold® Fletcher-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Fletcher type applicator is accepted by up-to-date clinical guidelines. The Kobold® Fletcher-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Henschke-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Henschke type applicator is accepted by up-to-date clinical guidelines. The Kobold® Henschke-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Vaginal Cylinder Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the vagina is accepted by up-to-date clinical guidelines. The Kobold® Vaginal Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

The CT Compatible / MR Unsafe HDR Kobold® Miami Cylinder Applicator Set is indicated for use in any patient case where high dose rate (HDR) radiation treatment of the cervix, vagina, and uterus with a Miami type applicator is acceptable by up-to-date clinical guidelines. The Kobold® Miami Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.

4.
Device Description:

The CT Compatible / MR Unsafe HDR Kobold® Fletcher-model Tandem and Ovoid Applicator Set design is based on the conventional modified Fletcher GYN applicator. Kobold manufactures versions compatible with HDR afterloaders. This applicator is mainly utilized for HDR radiation boosts to the cervix and parametrial tissues in conjunction with external beam radiation therapy. This GYN set consists of precision manufactured intrauterine tandems and a pair of interlocking vaginal colpostats with Fletcher type unshielded barrel or cylinder ovoids (all components are designed to allow for customization of the treated geometry). The distance between the two lateral ovoids is adjustable with a lock knob. Four differing tandem geometries are provided in the set: one straight, one with slight curvature, one with medium curvature, and one with maximal curvature. These allow for maximal accommodation of the uterine shape and flexure.

The CT Compatible / MR Unsafe HDR Kobold® Henschke-model Tandem and Ovoid Applicator Set design is based on the conventional modified Henschke GYN applicator. Kobold manufactures versions compatible with HDR afterloaders. This applicator is mainly utilized for HDR radiation boosts to the cervix and parametrial tissues in conjunction with external beam radiation therapy. This GYN set consists of precision manufactured intrauterine tandems and a pair of interlocking vaginal colpostats with Henschke type unshielded ovoids (all components are designed to allow for customization of the treated geometry). The distance between the ovoids is adjustable with a lock knob. Four differing tandem geometries are provided in the set: one straight, one with slight curvature, one with medium curvature, and one with maximal curvature. These allow for maximal accommodation of the uterine shape and flexure.

The CT Compatible / MR Unsafe HDR Kobold® Vaginal Cylinder Applicator Set design is based on conventional cylindrical HDR delivery systems with a connector interface compatible with major manufacturers' afterloaders. 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 precision manufactured vaginal cylinders of varied diameters for optimal radiation treatment delivery and anatomical customization.

The CT Compatible / MR Unsafe HDR Kobold® Miami Cylinder Applicator Set design is based on conventional modified Miami applicators with a connector interface compatible with major manufacturers' afterloaders. This applicator set 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. Various tandems are provided: straight, slight curvature, medium curvature, and maximal curvature. These allow for maximal accommodation of the uterine flexure.

5.
Substantial Equivalence Information:

Information presented supports substantial equivalence of CT Compatible / MR Unsafe HDR Kobold® Fletcher-model Tandem and Ovoid Applicator Set to the predicate device. The proposed device has similar indications for use, similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same general sterilization procedures.

Information presented supports substantial equivalence of CT Compatible / MR Unsafe HDR Kobold® Henschke-model Tandem and Ovoid Applicator Set to the predicate device. The proposed device has similar indications for use, similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same general sterilization procedures.

Information presented supports substantial equivalence of CT Compatible / MR Unsafe HDR Kobold® Vaginal Cylinder Applicator Set to the predicate device. The proposed device has similar indications for use, similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same general sterilization procedures

Information presented supports substantial equivalence of CT Compatible / MR Unsafe HDR Kobold® Miami Cylinder Applicator Set to the predicate device. The proposed device has similar indications for use, similar nature of body contact, is similar in shape and design, has the same fundamental technology and uses the same general sterilization procedures.

Please see predicate device brochures in **Appendix C** and previously cleared K123912 and K123941.

A. Predicate device name: Kobold® Fletcher Type Applicator Set, Kobold® Henschke Type Applicator Set, Kobold® Vaginal Cylinder Applicator Set, Kobold Sure-Guide Miami Cylinder Set
B. Predicate device K number: 123912, 123941
C. Comparison with predicate:

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	KOBOLD LLC
K-Number	K-160610	K-123912
Device Description	Applicator Set, Fletcher model	Applicator Set, Fletcher Type
Indications for Use	The CT Compatible / MR Unsafe HDR Kobold® Fletcher-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Fletcher type applicator is accepted by up-to-date clinical guidelines. The Kobold® Fletcher-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient	The CT/MRI Compatible HDR Henschke Type Applicator and Fletcher Type Applicator are indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.
Afterloader Compatibility*	Elekta: microSelectron®, Flexitron® Varian: GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.
Design Geometry	Flexible	Flexible
Materials	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl
Packing	Tray	Tray
Sterility	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions	Steam 4 min at 270ºF (132ºC), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented
Biocompatibility	Documented	Documented
Anatomical Sites	Uterus, Cervix	Uterus, Cervix
Environmental Compatibility	CT Compatible / MR Unsafe	CT/MRI Compatible

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	KOBOLD LLC
K-Number	K-160610	K-123912
Device Description	Applicator Set, Henschke model	Applicator Set, Henschke Type
Indications for Use	The CT Compatible / MR Unsafe HDR Kobold® Henschke-model Tandem and Ovoid Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus with a Henschke type applicator is accepted by up-to-date clinical guidelines. The Kobold® Henschke-model Tandem and Ovoid Applicator Set is intended for continuous use of up to 24 hours of contact with patient	The CT/MRI Compatible HDR Henschke Type Applicator and Fletcher Type Applicator are indicated for use in any case where high dose rate (HDR) radiation treatment of the cervix and uterus is accepted by up-to-date clinical guidelines.
Afterloader Compatibility	Elekta: microSelectron®, Flexitron® Varian: GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.
Design Geometry	Flexible	Flexible
Materials	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl
Packing	Tray	Tray
Sterility	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions	Steam 4 min at 270ºF (132ºC), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented
Biocompatibility	Documented	Documented
Anatomical Sites	Uterus, Cervix	Uterus, Cervix
Environmental Compatibility	CT Compatible / MR Unsafe	CT/MRI Compatible

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	KOBOLD LLC
K-Number	K160610	K-123941
Device Description	Vaginal Cylinder Applicator Set	Cylinder Set, Vaginal
Indications for Use	The CT Compatible / MR Unsafe HDR Kobold® Vaginal Cylinder Applicator Set is indicated for use in any case where high dose rate (HDR) radiation treatment of the vagina is accepted by up-to-date clinical guidelines. The Kobold® Vaginal Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.	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 for up-to-date clinical and practice guidelines.
Afterloader Compatibility	Elekta: microSelectron®, Flexitron® Varian: GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.
Materials	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl
Packing	Tray	Tray
Sterility	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions	Steam 4 min at 270ºF (132ºC), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented
Biocompatibility	Documented	Documented
Anatomical Sites	vagina	vagina
Environmental Compatibility	CT Compatible / MR Unsafe	CT/MRI Compatible

SUBSTANTIAL EQUIVALENCE TABLE	KOBOLD LLC	KOBOLD LLC
K-Number	K160610	K-123941
Device Description	Miami Cylinder Applicator Set	Cylinder Set, Miami
Indications for Use	The CT Compatible / MR Unsafe HDR Kobold® Miami Cylinder Applicator Set is indicated for use in any patient case where high dose rate (HDR) radiation treatment of the cervix, vagina, and uterus with a Miami type applicator is acceptable by up-to-date clinical guidelines. The Kobold® Miami Cylinder Applicator Set is intended for continuous use of up to 24 hours of contact with patient.	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 for up-to-date clinical and practice guidelines.
Afterloader Compatibility	Elekta: microSelectron®, Flexitron® Varian: GammaMed®, VariSource® with click-fit connector.	GammaMed®, VariSource® with click-fit connector.
Materials	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl	Titanium, Ultem®, Stainless Steel, Silicone, High Temperature Vinyl
Packing	Tray	Tray
Sterility	Provided Non-Sterile	Provided Non-Sterile
Sterilization Methods, Sterilization Conditions	Steam 4 min at 270ºF (132ºC), 44psi (3 bar) Dry 15 min.	Steam 18 min at 273ºF (134ºC), 44psi (3 bar) Dry 15 min; no Sterrad® compatibility documented
Biocompatibility	Documented	Documented
Anatomical Sites	cervix, vagina, and uterus	cervix, vagina, and uterus
Environmental Compatibility	CT Compatible / MR Unsafe	CT/MRI Compatible

6.

Test Principle, Performance Characteristics

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

7.

Bench Testing

Extensive testing in accordance with known standards is documented by the manufacturer for predicate device in K-123912 and K-123941. Standards specification for the materials used in surgical implant applications and predicate brachytherapy devices is in **Appendix A**. Finished device acceptance testing visual method sheets and performance tests are in **Appendix A**.

8.

Conclusions

The Kobold® Fletcher-model Tandem and Ovoid Applicator Set is similar in intended use and technological characteristics to the predicate device reviewed. The device is substantially equivalent with respect to indications for use and physical characteristics to the predicate device.

The Kobold® Henschke-model Tandem and Ovoid Applicator Set is similar in intended use and technological characteristics to the predicate device reviewed. The device is substantially equivalent with respect to indications for use and physical characteristics to the predicate device.

The Kobold® Vaginal Cylinder Applicator Set is similar in intended use and technological characteristics to the predicate device reviewed. The device is substantially equivalent with respect to indications for use and physical characteristics to the predicate device.

The Kobold® Miami Cylinder Applicator Set is similar in intended use and technological characteristics to the predicate device reviewed. The device is substantially equivalent with respect to indications for use and physical characteristics to the predicate device.

Contraindications: As per clinical guidelines and published and accepted standard clinical practice.

Warnings and Precautions: The precautions and warnings are provided in the device labeling for the Kobold® Fletcher-model Tandem and Ovoid Applicator Set, the Kobold® Henschke-model Tandem and Ovoid Applicator Set, the Kobold® Vaginal Cylinder Applicator Set, and the Kobold® Miami Cylinder Applicator Set.

9.

Summary

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

Based on the information submitted in this 510(k) application, the Kobold® Fletcher-model Tandem and Ovoid Applicator Set has been demonstrated to be substantially equivalent to the predicate device. The Kobold® Henschke-model Tandem and Ovoid Applicator Set has been demonstrated to be substantially equivalent to the predicate device. The Kobold® Vaginal Cylinder Applicator Set has been demonstrated to be substantially equivalent to the predicate device. The Kobold® Miami Cylinder Applicator Set has been demonstrated to be substantially equivalent to the predicate device.