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

Kobold, LLC
% Ms. Deanna Hughes
Director of Regulatory and Quality Systems
23403 E. Mission Avenue, Suite 220E
LIBERTY LAKE WA 99019

June 1, 2017

Re: K170203
Trade/Device Name: Kobold® Prostate HDR Template(s) and Kobold® Prostate HDR Stepper Template(s); Kobold® Interstitial Pencil Point Stainless Steel Needle Set(s) and Kobold® Interstitial Bevel Tip Stainless Steel Needle Set(s)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 26, 2017
Received: May 1, 2017

Dear Ms. Hughes:

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,

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

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)*
K170203

Device Name
Kobold® Prostate HDR Template(s) and Kobold® Prostate HDR Stepper Template(s)
Kobold® Interstitial Pencil Point Stainless Steel Needle Set(s) and Kobold® Interstitial Bevel Tip Stainless Steel Needle Set(s)

Indications for Use *(Describe)*
The Kobold Prostate HDR Template and Stepper Template are indicated for use as an accessory for high dose rate brachytherapy treatment of the prostate.

The Stainless Steel Interstitial Needles and corresponding stylets are indicated for use as an accessory for high dose rate brachytherapy treatment of the prostate.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. 510(k) Owner:

Kobold, LLC

2. Address:

23403 E. Mission Ave., Suite 220E
Liberty Lake, WA 99019

3. Contact Person:

Deanna Hughes, MS, RAC
Director of Regulatory and Quality Systems
Kobold, LLC
Email: deanna.hughes@koboldmedical.com
Direct: 818.321.0116

4. Date 510(k) Summary Prepared:

January 20, 2017

5. Trade Name:

Kobold Prostate HDR Template(s)
Kobold Prostate HDR Stepper Template(s)
Kobold Interstitial Pencil Point Stainless Steel Needle Set(s)
Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s)

6. Common Name:

System, Applicator, Radionuclide, Remote Controlled

7. Classification Name:

21 CFR § 892.5700, Remote controlled radionuclide applicator system (JAQ)

8. Classification Panel:

Radiology

9. Regulatory Classification:

Class II

10. Predicate Device(s):

HDR Prostrate Template and Accessories cleared in K091230 on August 12, 2009

11. Device Description:

Kobold Prostate HDR Templates and HDR Stepper Templates:
The Kobold Prostate HDR Template and Stepper Template are accessories to be used where ultrasound-guided interstitial temporary high dose rate (HDR)

brachytherapy treatment of the prostate is accepted by up-to-date clinical guidelines. The templates are ergonomically designed for freehand HDR technique. The templates are best used with biplanar transrectal ultrasound and confirmatory fluoroscopy.

The templates are single-use, disposable devices shipped nonsterile. It is customizable for almost any prostate size or shape. The templates include four suture holes at the corners to secure the template to the perineum. The templates are available in various gauge sizes to match the most common needles sizes. These devices are for continuous use of up to 24 hours of contact with the patient.

For workflows that require a stepper, the Kobold Prostate HDR Stepper Template fits into the Elekta Martinez Template Holder.

Kobold Stainless Steel Interstitial Needle Sets:
The stainless steel needles are 17 gauge in either a pencil point tip or a bevel tip. The associated stylets are inserted into needles to stiffen the needles during implantation of the needles into the patient and to stiffen the needles between radiation therapy fractions.

The Kobold Stainless Steel Interstitial Needles are intended for single use and are disposable. The maximum implantation time for these needles is less than 24 hours.

12. Indications for Use:

Kobold Prostate HDR Templates and HDR Stepper Templates:
The Kobold Prostate HDR Template and Stepper Template are indicated for use as an accessory for high dose rate brachytherapy treatment of the prostate.

Kobold Stainless Steel Interstitial Needle Sets:
The Stainless Steel Interstitial Needles and corresponding stylets are indicated for use as an accessory for high dose rate brachytherapy treatment of the prostate.

13. Technological Characteristics

The Kobold Prostate HDR Template(s), Kobold Prostate HDR Stepper Template(s), Kobold Interstitial Pencil Point Stainless Steel Needle Set(s), and Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s) have substantially equivalent indications for use, principle of operation, and technological characteristics as the *HDR Prostate Template and Accessories*, K091230.

The Kobold Prostate HDR Template(s), Kobold Prostate HDR Stepper Template(s), Kobold Interstitial Pencil Point Stainless Steel Needle Set(s), and Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s) have substantially equivalent fundamental scientific principles as the *HDR Prostate Template and Accessories*. The subject and predicate devices have substantially equivalent methods of template and needle use (principle of operation). The devices have substantially equivalent technological characteristics.

The use environment, target user, and patient population of the subject devices are the same as the predicate device.

14. Performance Data (Nonclinical)

The Kobold Prostate HDR Template(s), Kobold Prostate HDR Stepper Template(s), Kobold Interstitial Pencil Point Stainless Steel Needle Set(s), and Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s) was evaluated using biocompatibility, and bench testing to confirm the performance characteristics.

- Shelf Life - Real Time aging testing conducted shows that the templates included in this submission has an initial shelf life of 5 months.
- Biocompatibility – Cytotoxicity, Irritation, Sensitization, and Systemic Toxicity testing of the templates was conducted per ISO 10993. All testing passed.
- Performance Evaluation –The Non-Clinical Performance Bench Validation Testing demonstrated that the subject device met all predetermined acceptance criteria.

The data presented in this submission show that the subject devices will perform in a substantially equivalent manner to the predicate device.

Clinical trial data was not needed for these devices to show substantial equivalence.

15. Conclusion

The Kobold Prostate HDR Template(s), Kobold Prostate HDR Stepper Template(s), Kobold Interstitial Pencil Point Stainless Steel Needle Set(s), and Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s) successfully met all predetermined acceptance criteria for the design validation.

The Kobold Prostate HDR Template(s), Kobold Prostate HDR Stepper Template(s), Kobold Interstitial Pencil Point Stainless Steel Needle Set(s), and Kobold Interstitial Bevel Tip Stainless Steel Needle Set(s) is substantially equivalent to the legally marketed predicate device and does not raise any new safety or effectiveness questions.