Geomed Medizin-Technik GmbH & Co. KG
℅ Ms. Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Aalsmeerweg 123-3
Amsterdam, Noord-Holland 1059AH
THE NETHERLANDS

July 10, 2020

Re: K201279
Trade/Device Name: ASSISTO® Universal Applicator Clamping Device
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ, GWG, and GCJ
Dated: May 12, 2020
Received: May 13, 2020

Dear Ms. Scherp:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201279

Device Name
ASSISTO® Universal Applicator Clamping Device

Indications for Use *(Describe)*
The ASSISTO® Universal Applicator Clamping Device is indicated for use as an accessory for HDR or PDR brachytherapy treatment.

Specifically, it is intended to hold dedicated applicator holding devices by Varian Medical Systems in place during cancer treatment of the vagina, vaginal stump, rectum, cervix, uterus and endometrium using HDR or PDR brachytherapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary of Safety and Effectiveness K201279

Date: June 15, 2020

Submitter:

Name:	Geomed Medizin-Technik GmbH & Co. KG
Address:	Ludwigstaler Strasse 27 D-78532 Tuttlingen Germany
Contact Person:	Hanno Haug
Telephone:	+49.7461.93550

Product:

Name of Device:	ASSISTO® Universal Applicator Clamping Device
Common Name:	Holding Accessory for Applicator System
Classification Name:	Remote Controlled Radionuclide Applicator System
Regulatory Class:	II
21 CFR Section:	892.5700

Predicate Device: K170203 – Kobold® Prostate HDR Template(s) and Kobold® HDR Stepper Template(s)

Reference Device: K052745 – ASSISTO® Arm Systems

Device Description: The ASSISTO® Universal Applicator Clamping Device is a self-retaining device that consists of a stainless steel tubular, articulated arm connected to a vertical stand. The arm is freely adjustable within the articulating radius. A screw clamp mounted on the distal end of the device serves to hold dedicated applicator holding devices by Varian Medical Systems in place during cancer treatment of the vagina, vaginal stump, rectum, cervix, uterus and endometrium using HDR or PDR brachytherapy. Two accessories, a stainless steel clamp socket and a base plate manufactured of thermoplastic and stainless steel, are provided to table-mount the device during clinical use.

The ASSISTO® Universal Applicator Clamping Device and the clamp socket are reusable and provided non-sterile for cleaning and sterilization by the user before use. The non-sterile, reusable base plate is intended for cleaning and disinfection by the user before use.

Indications for Use: The ASSISTO® Universal Applicator Clamping Device is indicated for use as an accessory for HDR or PDR brachytherapy treatment.

Specifically, it is intended to hold dedicated applicator holding devices by Varian Medical Systems in place during cancer treatment of the vagina, vaginal stump, rectum, cervix, uterus and endometrium using HDR or PDR brachytherapy.

Comparison Table:

	Subject Device	***Predicate Device***	***Reference Device***
Trade Name	ASSISTO® Universal Applicator Clamping Device	Kobold® Prostate HDR Template(s) and Kobold® HDR Stepper Template(s)	ASSISTO® Arm Systems Model No. CA 235-30-01
510(k) Number	K201279	K170203	K052745
Manufacturer	Geomed Medizin-Technik	Kobold, LLC	Geomed Medizin-Technik GmbH & Co.

Indications for Use	The ASSISTO® Universal Applicator Clamping Device is indicated for use as an accessory for HDR or PDR brachytherapy treatment. Specifically, it is intended to hold dedicated applicator holding devices by Varian Medical Systems in place during cancer treatment of the vagina, vaginal stump, rectum, cervix, uterus and endometrium using HDR or PDR brachytherapy.	The Kobold® Prostate HDR Template(s) and Kobold® HDR Stepper Template(s) are indicated for use as an accessory for high dose rate brachytherapy treatment of the prostate.	ASSISTO® Arm Systems consist of a table-mounted endoscope holder system intended for use by surgeons to hold endoscopes and arthroscopes with a diameter of 2.7mm to 10mm during general diagnostic and therapeutic procedures. The device is also intended for use by qualified surgeons for holding endoscopes during diagnostic and therapeutic neurologic procedures.
Design	Tubular, articulated arm connected to a vertical, table-mounted stand and provided with a screw-clamp holding component. The position of the articulated arm is freely adjustable within the articulating radius.	Template provided with holes in a grid array and a locking mechanism to lock needles in place. The template is equipped with four suture holes to secure it to the perineum during use.	Tubular, articulated arm connected to a vertical, table-mounted stand and provided with a selection of screw clamp holding components. The position of the articulated arms is freely adjustable within the articulating radius.
Working Length	310 mm	N/A	310 mm
Materials	Stainless steel and thermoplast polyamid	N/A	Stainless steel and thermoplast polyamid
Patient Contact	No patient contact	Intact skin	No patient contact
Sterility	Non-sterile	Non-sterile	Non-sterile
Reusable	Yes	No	Yes

Performance Testing: Design verification and validation testing to support determination of substantial equivalence consisted of the following tests:

- Verification of the device's capacity to securely hold the Varian Medical Systems applicator holding devices.
- Validation testing of the recommended end user device reprocessing procedures

Acceptance criteria were met for all tests performed.

Conclusion: The information provided in this 510(k) submission, including results of nonclinical testing, indicates that the ASSISTO® Universal Applicator Clamping Device is substantially equivalent to the predicate device.