April 22, 2022

Avanos Medical, Inc.
% Angela Cushman
Senior Vice President, QA/RA (Interim)
5405 Windward Parkway
Alpharetta, GA 30004

Re: K220588
Trade/Device Name: Avanos* CORTRAK* 2 Enteral Access System (EAS)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: February 28, 2022
Received: March 1, 2022

Dear Angela Cushman:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220588

Device Name
Avanos* CORTRAK* 2 Enteral Access System (EAS)

Indications for Use *(Describe)*
The Avanos* CORTRAK*2 Enteral Access System (EAS) utilizes tube tracking technology to assist, in conjunction with institution protocols, qualified clinicians in guiding placement of Avanos Medical CORTRAK*2 feeding tubes of 8FR or greater into the stomach or small bowel of patients requiring enteral feeding.

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 - K220558

Avanos* CORTRAK* 2 Enteral Access System (EAS)

1. SUBMITTER

Avanos Medical, Inc.
5405 Windward Parkway
Alpharetta, Georgia 30004, U.S.A.

Correspondent Name: Angela Cushman
Senior VP, RAQA (Interim)
706-344-8678
angela.cushman@avanos.com

Date Prepared: April 7, 2022

2. Device

Name of Device:	Avanos* CORTRAK* 2 Enteral Access System (EAS)
Common or Usual Name:	Enteral Access Device
Classification Name:	Gastrointestinal tube and accessories
Regulation:	21 CFR § 876.5980
Regulatory Class:	II
FDA Product Code:	KNT

3. Predicate Device

CORTRAK* 2 Equilateral EAS (K191340)

4. Description of Device

Avanos* CORTRAK* 2 Enteral Access System (EAS) device is designed to track the path of an 8 Fr or greater Avanos Medical feeding tube tip during the patient placement procedure. A coil winding at the distal end of the transmitting stylet acts as a transmitter, and its signal is detected by the externally positioned receiver unit. The received signals are input to the attached Monitor unit. The resulting raw data is processed, recorded, and presented to the operator in a meaningful and intuitive screen tracing. The Avanos* CORTRAK*2 EAS device is an electrical device that does not contact the patient, is not sterilized, and is reusable. Like the predicate device, it is intended to be used in a clinical environment by qualified trained clinicians.

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5. Intended Use

The Avanos* CORTRAK*2 Enteral Access System (EAS) assists qualified clinicians to guide NG/NI feeding tubes into the stomach or small bowel of patients requiring enteral feeding.

6. Indications for Use

The Avanos* CORTRAK*2 Enteral Access System (EAS) utilizes tube tracking technology to assist, in conjunction with institution protocols, qualified clinicians in guiding placement of Avanos Medical CORTRAK*2 feeding tubes of 8FR or greater into the stomach or small bowel of patients requiring enteral feeding.

7. Technological Characteristics

The Avanos* CORTRAK* 2 Enteral Access System is substantially equivalent to the predicate device CORTRAK* 2 Equilateral EAS (K191340).

The only change to the subject device involves labeling updates. Labeling updates include a change to the indications for use to clarify the inclusion of a secondary confirmatory method for tube placement per institution protocols, and enhanced warnings in a consolidated organized section.

There were no other changes in the design, materials, performance, and technological characteristics from the predicate device.

The difference in the updated labeling has no impact on the intended use, technological principles, safety, or effectiveness of the subject device when compared to the predicate device.

8. Substantial Equivalence Discussion

Intended Use Comparison

Predicate Indication for Use (K191340) CORTRAK*2 Equilateral EAS	**Predicate Intended Use (K191340)** CORTRAK*2 Equilateral EAS	**Subject Indication for Use (K220558)** Avanos* CORTRAK*2 EAS	**Subject Intended Use (K220558)** Avanos* CORTRAK*2 EAS
CORTRAK* 2 Equilateral Enteral Access System is an electrical device designed to aid qualified operators in the placement of Avanos NG feeding tubes of 8 FR or greater into the stomach or small bowel of patients	Assists qualified operators to guide NG/NI feeding tubes into stomach or small bowel.	The Avanos* CORTRAK*2 Enteral Access System (EAS) utilizes tube tracking technology to assist, in conjunction with institution protocols, qualified clinicians in guiding placement of Avanos Medical CORTRAK*2 feeding tubes of 8FR or	Assists qualified clinicians to guide NG/NI feeding tubes into stomach or small bowel.

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Predicate Indication for Use (K191340) CORTRAK*2 Equilateral EAS	Predicate Intended Use (K191340) CORTRAK*2 Equilateral EAS	Subject Indication for Use (K220558) Avanos* CORTRAK*2 EAS	Subject Intended Use (K220558) Avanos* CORTRAK*2 EAS
requiring enteral feeding. CORTRAK* 2 Equilateral Enteral Access System can be used to confirm placement of feeding tubes prior to commencing the delivery of enteral nutrition.		greater into the stomach or small bowel of patients requiring enteral feeding.	

Conclusion:
The change in the Indications for Use does not change the Intended Use of assisting qualified operators to guide NG/NI feeding tubes into the stomach or small bowel.

The Indications for Use change does not raise different or new questions of safety and effectiveness.

Technologic Characteristics Comparison

The labeling changes have no effect on the technologic characteristics. The labeling difference has no impact on the intended use, technological principles, safety, or effectiveness of the subject device when compared to the predicate device. The device design, material, and operating principle remain the same as the predicate device CORTRAK* 2 Equilateral EAS (K191340).

9. Summary of Non-Clinical Testing

Non-clinical verification of the labeling change was conducted through the risk management process according to ISO 14971:2019. The risk management file was updated to eliminate risks associated with the use of Avanos* CORTRAK*2 EAS as a confirmatory method for the placement of CORTRAK*2 NG/NI feeding tubes. The risk profile of the device system did not have a significant impact due to the labeling updates.

There were no other non-clinical tests performed for the labeling updates for the subject device.

10. Conclusion

The difference between the predicate CORTRAK* 2 Equilateral Enteral Access Device (K191340) and subject Avanos* CORTRAK*2 Enteral Access System (EAS) (K220588) do not raise any new or different questions of safety or effectiveness. The subject Avanos* CORTRAK*2 Enteral Access System (EAS) is substantially equivalent to the predicate CORTRAK*Equilateral Enteral Access Device cleared under K191430 with respect to the intended use, technology, operating principle, material composition, and performance.