June 4, 2019

Avanos Medical, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
Warren, NJ 07059

Re: K191340
Trade/Device Name: CORTRAK* 2 Equilateral Enteral Access System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 14, 2019
Received: May 20, 2019

Dear Dave Yungvirt:

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.
Acting Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191340

Device Name
CORTRAK*2 Equilateral Enteral Access System

Indications for Use *(Describe)*
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 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.

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

X 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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S10(K) SUMMARY - SPECIAL 510(k)

Preparation Date: May 14, 2019

Submitter's/Manufacturer's Name, Address, Telephone, Contact Person

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

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Monica.king@avanos.com

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade/Device Name:	CORTRAK* 2 Equilateral Enteral Access System
Common/Usual Name:	Enteral Access Device
Regulation Name:	Gastrointestinal tube and accessories
Regulation Number:	21 CFR § 876.5980
FDA Product Code:	KNT
Regulatory/Device Class:	Class II

2. PREDICATE DEVICE

CORTRAK 2* Enteral Access Device, (K113351)

3. INDICATIONS FOR USE

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 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.

4. DEVICE DESCRIPTION

CORTRAK* 2 Equilateral Enteral Access System (EAS) device is designed to track the path of an 8 Fr or greater Avanos 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 All-In-One Monitor unit. The resulting raw data is processed, recorded, and presented to the operator in a meaningful and intuitive screen tracing. The CORTRAK*2 Equilateral 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 use in clinical environment.

5. TECHNOLOGICAL CHARACTERISTICS

The CORTRAK*2 Equilateral Enteral Access Device is substantially equivalent to the predicate device. The following changes from the predicate device were made:

- Updated PC Single Board Computer
- Updated Display Processor Module
- Updated Operating System
- Graphical User Interface (GUI) updated to better match current display conventions (e.g., button shapes, font, etc.)
- Removed ability to boot system from USB port
- Removed requirement for battery conditioning

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

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

Intended Use Comparison

The following table provides a comparison between the intended use of the subject device and predicate device.

Property	Predicate Device (K113351)	Subject Device	Comments
Indications for Use	The CORTRAK* 2 System is an electrical device designed to aid qualified operators in the placement of the CORPAK MedSystems feeding tubes of 8 FR or greater into the stomach or small bowel of patients requiring enteral feeding. CORTRAK* 2 can be used to confirm placement of feeding tubes prior to commencing the delivery of enteral nutrition.	CORTRAK* 2 Equilateral Enteral Access System is an electrical device designed to aid qualified operators in the placement of Avanos feeding tubes of 8 FR or greater into the stomach or small bowel of patients 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.	Same (updated only to reflect new branding)
Contraindications	DO NOT use the CORTRAK* 2 Enteral Access System for patients with implanted medical devices that may be affected by electromagnetic fields.	DO NOT use the CORTRAK* 2 Equilateral Enteral Access System for patients with implanted medical devices that may be affected by electromagnetic fields.	Same
Acceptable NG Tube size	8 Fr or greater	8 Fr or greater	Same
Prescription Status	Rx Only	Rx Only	Same

Environment of Use	For use within clinical setting	For use within clinical setting	Same

Discussions of differences in Indications for Use Statement
The Indications for Use statement was modified to reflect the new ownership and branding of the subject device (i.e., Avanos Medical). These differences have no impact on the intended use, safety, or effectiveness of the subject device when compared to the predicate device.
Technological Characteristics Comparison
The following tables provides a comparison between the technological characteristics of the subject device and predicate device.

Property	**Predicate Device (K113351)**	**Subject Device**	**Comments**
Sterilization	Non-Sterile	Non-Sterile	Same
Electronics	PC Single Board Computer, Qseven, 1.6GHz Intel Atom Z530, 1GB DDR2 memory, SATA	PC Single Board Computer, Qseven, 1.75 GHz Dual Core Intel Atom E3827, 2GB DDR3, 4GB eMMC. BIOS: Congatec Utility version 1.5.6	Updated to resolve obsolescence of components
Software - Display Processor Module Software - Operating System	Slackware distribution of the Linux Operating System. The OS is a custom build of the Slackware kernel version 2.6.34.	Changed to QNX Medical Kernel version 1.1 to enable use of new Single Board Computer and to improve future expansion and maintenance.	Updated to resolve obsolescence of components
Software - IT Security	Bootable from USB	Not bootable from USB	Security Enhancement
Software - Graphical User Interface	Device displays a Graphical User Interface on a touch screen. Platform is an FLTK based application	Device displays a Graphical User Interface on a touch screen. Minor changes in look and feel, including button shapes and font.	Updated to resolve obsolescence of components
Power Requirements	External Power Supply Input: 100-250 Volts AC, 50-60 Hz, 140 VA Output: 15 VDC, 4A Battery: 11.1 Volts, 6.6 Ampere-hour Li-Ion rechargeable smart battery with thermal overload protection.	External Power Supply Input: 100-250 Volts AC, 50-60 Hz, 140 VA Output: 15 VDC, 4A Battery: 11.1 Volts, 6.6 Ampere-hour Li-Ion rechargeable smart battery with thermal overload protection.	Same

Property	Predicate Device (K113351)	Subject Device	Comments
Battery Operation	New battery, when fully charged, will operate the device in continuous placement mode for approximately two hours. Charging an empty rechargeable battery to full capacity will take approximately 4-6 hours when the Monitor Unit is off. The expected life for a rechargeable battery is approximately 2 years.	New battery, when fully charged, will operate the device in continuous placement mode for approximately two hours. Charging an empty rechargeable battery to full capacity will take approximately 4-6 hours when the Monitor Unit is off. The expected life for a rechargeable battery is approximately 2 years.	Same
Battery Conditioning	Present	Not Present in unit since battery is self-conditioning	Battery conditioning occurs in both
Environmental Operating Conditions	Operating Temperature Range: 59ºF (15ºC) to 100ºF (38ºC). Relative Humidity Range: 30% to 90%.	Operating Temperature Range: 59ºF (15ºC) to 100ºF (38ºC). Relative Humidity Range: 30% to 90%.	Same
Dimensions	All-In-One Monitor: 12.20” W x 13.30” H x 3.30” D Smart Receiver Unit: 5.60” W x 5.60” H x 1.90” D	All-In-One Monitor: 12.20” W x 13.30” H x 3.30” D Smart Receiver Unit: 5.60” W x 5.60” H x 1.90” D	Same
Weight	All-In-One Monitor with Pole Clamp: Approx. 8.0 lbs. Smart Receiver Unit: Approx. 0.5 lbs. Utility Basket: Weight capacity 10 lbs.	All-In-One Monitor with Pole Clamp: Approx. 8.0 lbs. Smart Receiver Unit: Approx. 0.5 lbs. Utility Basket: Weight capacity 10 lbs.	Same
System security requires user passwords for access	Present	Present	Same
Interface to clinical information systems	None	None	Same

Discussions of technological differences
The changes that resulted in technological differences were made to resolve obsolescence of certain electronic componentry and software. These differences have

no impact on the intended use, technological principles, safety, or effectiveness of the subject device when compared to the predicate device.

7. SUMMARY OF NONCLINICAL TESTING

Performance testing on the device under submission was conducted to demonstrate the modified device continued to meet performance specifications. Results of design verification and validation activities did not raise any new issues of safety or effectiveness. Non-clinical verification was conducted through the risk management process according to ISO 14971:2012. The following verification tests were conducted:

Testing Requirements	Result
Compliance to IEC 60601-1 (Medical Electrical Equipment – General Requirements for basic safety and essential performance 2012, Edition 3.1, Class 1.	Pass
Compliance to IEC 60601-1-2 (Medical Electrical Equipment - General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.	Pass
Compliance to IEC 62366-1:2015 (Part 1: Application of Usability Engineering to Medical Devices.)	Pass
Compliance to IEC 62304:2006 (Medical device software – software life cycle processes)	Pass

8. OVERALL PERFORMANCE CONCLUSIONS

The above nonclinical studies demonstrate CORTRAK*2 Equilateral Enteral Access Device is substantially equivalent to the predicate CORTRAK* 2 Enteral Access Device **(K113351)** in intended use, design, materials, performance, and biocompatibility attributes. There are no new questions of safety and effectiveness as compared to the predicate device.

9. CONCLUSION

The differences between the predicate CORTRAK* 2 Enteral Access Device (K113351) and subject CORTRAK*2 Equilateral Enteral Access Device do not raise any new or different questions of safety or effectiveness. The subject CORTRAK*2 Equilateral Enteral Access Device is substantially equivalent to the predicate CORTRAK*Enteral Access Device cleared under K113351 with respect to the indications for use, technology, material composition, and performance.