

510(k) SUMMARY - K220558

Avanos* CORTRAK* 2 Enteral Access System (EAS)

1. SUBMITTER

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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.



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)	Predicate Intended Use (K191340)	Subject Indication for Use (K220558)	Subject Intended Use (K220558)
CORTRAK*2 Equilateral EAS	CORTRAK*2 Equilateral EAS	Avanos* CORTRAK*2 EAS	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.



Predicate Indication for Use (K191340)	Predicate Intended Use (K191340)	Subject Indication for Use (K220558)	Subject Intended Use (K220558)
CORTRAK*2 Equilateral EAS	CORTRAK*2 Equilateral EAS	Avanos* CORTRAK*2 EAS	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.