DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 oradevices2firmresponse@fda.hhs.gov	12/5/2023-12/15/2023* FEI NUMBER 3011270181

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Angela F. Cushman, Senior Vice President, Quality	
FIRM NAME Avanos Medical, Inc.	STREET ADDRESS 5405 Windward Pkwy
CITY, STATE, ZIP CODE, COUNTRY Alpharetta, GA 30004-3894	TYPE ESTABLISHMENT INSPECTED Specification Developer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically,

The procedure Corrective and Preventive Action (CAPA) Request Process (PR-09629, Rev. 9, effective date Sep 9, 2022) was not adequately implemented as evidenced by,

A. Your firm failed to investigate the root cause of CAPA-2022-0002, as required by Section 6.3 of the procedure. The CAPA was initiated to manage updates to the intended use and labeling of the CORTRAK* 2 Enteral Access System (EAS) to address adverse events of lung placement of nasogastric (NG) tubes while using the CORTRAK EAS System that led to a Class I recall (Z-1032-2022).

   There is no documentation in the CAPA record to demonstrate an investigation was completed to identify potential causes and commonalities of the adverse events such as product design, clarity of instructions for use, software version, user training, use scenarios (i.e. agitated patients, receiver unit placement, etc.), or patient population (i.e. atypical anatomy, obese patients, etc.). Furthermore, the investigation does not include an evaluation to determine how the NG Tube

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Stylet may be a contributing factor to the adverse events.

B. Your firm failed to develop an effectiveness monitoring plan for CAPA-2022-0004 that identifies monitoring activities that will be executed to measure the effectiveness of the implemented corrective and/or preventive actions to eliminate or minimize the recurrence of the identified root causes or potential causes as required by Section 6.9 and Section 4.6 of the procedure. The documented plan is a summary of specific activities/procedures that were implemented as part of the CAPA and does not define how it will be determined that the actions taken were effective in reducing the number of adverse events associated with the CORTRAK EAS. The CAPA was closed as effective on June 4, 2023

C. Your firm failed to document or reference all objective evidence supporting the root cause investigation activities (results (test data), methods, meetings, minutes, etc.) in the record for CAPA 2023-0002 as required by Section 6.3.5 of the procedure. The CAPA was initiated to address complaints involving cracks on the Y-manifold and elbow-manifold of the BALLARD ACCESS Closed Suction System for Neonates/Pediatrics which led to the initiation of a Class I recall (Z-1189-2023/Z-1190-2023). The potential root causes identified in the CAPA record are 1) the (b) (4) of the manifold is (b) (4) , 2) The process for (b) (4) the manifold has (b) (4) and 3) The (b) (4) does is not capable of (b) (4) There is no documentation in the CAPA record to support these conclusions or to demonstrate if an investigation was conducted to determine a potential failure within the design and development process which may have contributed to the root cause.

OBSERVATION 2

Risk analysis is inadequate.

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Specifically,

A. The CORTRAK 2 System USE FMEA (DHFE-09602, Rev. 2, May 31, 2023) and DH CORTRAK System Hazard Analysis (DHFE-09521, Rev. 3, effective date Dec. 4, 2023) do not address the scenario of the receiver unit for the CORTRAK Enteral Access System (EAS) falling off or shifting during a placement of a nasogastric (NG) tube. The receiver unit falling off during placement of an NG tube on an agitated/combative patient that resulted in a lung placement was reported in COMP-GHC-23-03497.

B. The risk analysis conducted as part of complaint evaluations does not adequately address when more than one failure mode could lead to patient harm. For example,
   1. COMP-GHC-23-03356 was opened on 07/27/2023 for a customer complaint reporting lung placement of NG tube during use of the CORTRAK EAS which resulted in lung feeding. The complaint investigation identified the following failure modes may have contributed to the complaint event 1) tracing started too early, 2) artifact on placement screen due to user not properly erasing the trace after pull back, 3) receiver unit is not placed correctly, and 4) feeding tube location was not confirmed. Only the failure mode of "feeding tube location was not confirmed" was evaluated as part of the risk assessment and not the failure modes that contributed to the lung placement.

   2. COMP-GHC-23-02948 was opened on 07/05/2023 for a reported lung placement of a CORTRAK NG tube during use of the CORTRAK EAS. The complaint investigation identified the following failure modes may have contributed to the complaint situation 1) tracing started too early, 2) artifact on placement screen due to user not properly erasing the trace after pull back, 3) receiver unit is not placed correctly, and 4) feeding tube in wrong location. Only the failure mode of "feeding tube in wrong location" was evaluated as part of the risk assessment and not the failure modes that contributed to the lung placement.

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C. Your firm failed to update CORTRAK 2 System USE FMEA (DHFE-09602, Rev. 2, May 31, 2023 (version effective at time of complaints)) when complaint information suggests a previously identified hazardous situation or use error may lead to a different failure mode. For example,

1. COMP-GHC-23-02948 was opened on 07/05/2023 for a reported lung placement of a CORTRAK NG tube during use of the CORTRAK EAS. In the risk assessment section of the complaint record the selected failure mode is "Feeding tube placed in wrong location" and the use error is "User begins feeding after wrongly confirming location of the feeding tube using institution's confirmation method". In the Use FMEA, the use error of "User begins feeding after wrongly confirming location of the feeding tube using institution's confirmation method" is associated with the failure mode "Feeding tube is blindly placed". Your firm failed to update the Use FMEA when it was determined that that a previously identified use error could be associated with a different failure mode.

2. COMP-GHC-23-03497 was opened on 08/08/2023 for a reported lung placement of a CORTRAK NG tube during use of the CORTRAK EAS. In the risk assessment section of the complaint record the selected failure mode is "Feeding tube placed in wrong location" and the hazardous situation is "Excessive force used during device placement/removal". In the Use FMEA the hazardous situation of "Excessive force used during device placement/removal" is associated with the failure mode "Feeding tube penetrates patient". Your firm failed to update the Use FMEA when it was determined that that a previously identified hazardous situation could be associated with a different failure mode.

OBSERVATION 3

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Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

The procedure Global Complaint Handling Management (PR-11302, Rev. 16, effective date July 17, 2023) does not ensure that complaint investigations are adequately conducted and complaint information is adequately documented, as evidenced by:

A. Root cause codes assigned to complaints do not adequately document the actual root cause of the complaint. For example, "incorrect use" is routinely assigned as the root cause for complaints involving nasogastric (NG) tube lung placements that occurred while using the CORTRAK EAS. "Incorrect use" may be associated with incorrect placement of the receiver unit (COMP-GHC-23-03356, COMP-GHC-23-02948), failure to erase tracings after pull back which may cause placement confusion (COMP-GHC-23-03356, COMP-GHC-23-02948), misinterpretation of CORTRAK display output (COMP-GHC-22-02400, COMP-GHC-23-03356, COMP-GHC-01734, COMP-GHC-22-03264, COMP-GHC-02234), starting the tracing too early (COMP-GHC-23-03356, COMP-GHC-23-02948) or use on combative/agitated patient (COMP-GHC-22-02400, COMP-GHC-23-03497). Assigning the same root cause of "incorrect use" for these different scenarios does not allow for adequate analysis of what function of the system users may be improperly trained on or do not understand how to use correctly or where additional safety features may need to be designed into the device.

B. You failed to conduct and document results of complaint investigations as required by the procedure. For example,

    1. COMP-GHC-21-01418 and COMP-GHC-21-01734 were opened to document customer complaints after the MIC-KEY SF Gastronomy Feeding Tube was reintroduced to the market following a design change to correct device malfunctions identified in Class II

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Recall Z-2969-2020. For both complaints, no root cause was identified, and an investigation was not documented to determine if the device malfunctions were caused by the design change.

2. COMP-GHC-23-01486, COMP-GHC-23-03629, and COMP-EHC-22-00261 were opened to document customer complaints reporting unexpected, sporadic, or sluggish tracings while using the CORTRAK EAS. For all three complaints, your firm received the tracing files for evaluation; however, there is no documentation in the complaint record to demonstrate that the tracing files were reviewed as part of the complaint investigations.

3. COMP-GHC-01734 was opened on 04/19/2023 to document the following four complaints received from one customer regarding the CORTRAK EAS: 1) lung placement while using the system, 2) error code "critical error" and shutting down right away, 3) green dot does not always advance when advancing tube (without resistance), and 4) tube placement on the screen does not match x-ray taken (tube placed in upper stomach but x-ray looks placed in lower stomach). Your firm only investigated the complaint of lung placement and failed to investigate the additional three reported complaints.

C. The procedure does not ensure that all relevant complaint information is collected to adequately conduct a complaint investigation. For example, when a customer reports that tracings from a complaint involving use of the CORTRAK EAS system are too large to send by email, you do not have a process to consistently ensure that the customer is provided with alternate method for sending the tracings. Furthermore, you do not have a process to consistently ensure a copy of the final tracing printout is requested as an alternate means to review tracing data when the tracing files cannot be provided.

***DATES OF INSPECTION**

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12/05/2023(Tue), 12/06/2023(Wed), 12/07/2023(Thu), 12/08/2023(Fri), 12/11/2023(Mon), 12/12/2023(Tue), 12/13/2023(Wed), 12/14/2023(Thu), 12/15/2023(Fri)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

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