KENTEC® MEDICAL, INC.

APR 22 2010

SUMMARY OF SAFETY & EFFECTIVENESS

This 510k summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

APPLICANT	Kentec Medical, Inc. 17871 Fitch Irvine, CA 922614 Tel: 949-863-0810 Fax: 949-833-9730
OFFICIAL CORRESPONDENT	Keith Rooks QA/RA Manager Tel: 949-863-0810 Fax: 949-833-9730 Kjrooks@kentecmedical.com
TRADE NAME	Ameritus® Entral™ Polyurethane Feeding Tube Ameritus® Entral™ Silicone Feeding Tube
COMMON OR USUAL NAME	Feeding Tube
CLASSIFICATION NAME	Gastrointestinal Tubes and accessories
DEVICE CLASSIFICATION	Class II per 21CFR §876.5980
PRODUCT CODE	FPD
PREDICATE DEVICE NAMES	NeoMed Polyurethane Enteral Feeding Tube (K082238) NeoMed Silicone Enteral Feeding Tube (K072881)

SUBSTANTIAL EQUIVALENCE

The Ameritus Entral™ Feeding Tubes made of either Polyurethane or Silicone are substantially equivalent to the Neomed Polyurethane and Silicone Enteral Feeding Tubes.

The devices have the same method of operation, delivery of fluids including liquid nutrition media and medication through single lumen catheter. Bench testing demonstrated that Ameritus Entral™ Feeding Tubes made of either Polyurethane or Silicone are functionally equivalent to the predicate devices and that any minor differences do not affect safety or effectiveness.

DESCRIPTION OF DEVICE

The Ameritus Entral™ Feeding Tubes are composed of two families of Feeding Tubes each made with different materials: polyurethane and silicone. The two families of Feeding Tubes are all made with a single lumen catheter that is used to deliver fluids as prescribed by the physician including liquid nutritional media and/or medication.

The Ameritus Entral™ Feeding Tubes are sterile, individually packaged, Latex Free and DEHP Free. The orange color coding provides easy visual recognition of the enteral connection. The Ameritus Entral™ Feeding

Tubes are designed with a Radiopaque stripe for X-ray visualization to confirm proper feeding tube placement. French size and length clearly printed on the feeding tube as well as centimeter markings (approx.) to assist tube placement or check for migration. A Tethered plug for connector closure is incorporated to prevent air and fluid ingress when not in use.

The device consists of the following main components: A feeding tube single lumen catheter and a connector with molded closure plug.

INDICATIONS FOR USE
The Amertius Entral™ Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients, and is not intended for use beyond 30 days.

PERFORMANCE DATA
Both design verification and performance test results demonstrated that Ameritus Entral™ Feeding Tube two families made of either Polyurethane or Silicone performed as per their intended use and are equivalent to their respective predicate devices.

CONCLUSION
Based on performance testing test results, Kentec Medical can conclude that the Ameritus Entral™ Feeding tube two families made of either Polyurethane or Silicone are equivalent to their respective predicate device with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Mr. Keith Rooks
RA/QA Manager
Kentec Medical, Inc.
17871 Fitch
IRVINE CA 92614

APR 22 2010

Re: K100526
Trade/Device Name: Ameritus Entral™ Feeding Tubes
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: April 13, 2010
Received: April 13, 2010

Dear Mr. Rooks:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K100526

Device Name: Ameritus Entral™ Feeding Tubes

Indications For Use:

The Amertius Entral™ Feeding Tube is intended for nasogastric or orogastric delivery of various types of liquid nutritional media through the gastro intestinal tract of neonatal and small pediatric patients, and is not intended for use beyond 30 days.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100526