DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 30, 2015

Applied Medical Technology, Inc.
Joshua Meinke
QA/Regulatory Supervisor
8000 Katherine Boulevard
Brecksville, OH 44141

Re: K142989
Trade/Device Name: AMT Mini ONE® Enteral Extension Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: October 30, 2014
Received: November 3, 2014

Dear Joshua Meinke,

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION – 4

c. – INDICATIONS FOR USE STATEMENT

510(k) Number: K142989

Trade Name: AMT Mini ONE® Enteral Extension Set
Common Name: Enteral Extension Set

Indications for Use:

The Mini ONE® Enteral Extension Set is intended for use as an extension set for the Mini ONE® Gastrostomy Button, G-Jet Gastrojejunal Feeding Tube, Mic-Key® Secure-Lok® feeding devices, or other compatible enteral feeding devices. The extension set is for administering feeding, medications, and decompression to compatible devices.

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

SECTION – 5

510(K) Summary

AMT Mini ONE® Enteral Extension Set

Date Prepared:	January 29, 2015
Submitter:	Joshua D. Meinke QA/Regulatory Supervisor Applied Medical Technology, Inc. 8006 Katherine Boulevard Brecksville, OH 44141 Phone: 440-717-4252 Fax: 440-717-4200 Email: Josh.Meinke@appliedmedical.net Contact Person: Joshua Meinke
Device Information:	Trade Name: AMT Mini ONE® Enteral Extension Set Common Name: Enteral Extension Set Classification Name: Gastroenterology and Urology (21 CFR 876.5980) Regulatory Class: II Product Code: PIF - Gastrointestinal Tubes with Enteral Specific Connectors
Predicate Device:	AMT Low Profile Feeding Set Accessory (Applied Medical Technology, Inc.) (cleared under K971757)
Intended Use:	The Mini ONE® Enteral Extension Set is intended for use with compatible enteral feeding devices for administration of feeding, medications, and decompression.
Indications for Use:	The Mini ONE® Enteral Extension Set is intended for use as an extension set for the Mini ONE® Gastrostomy Button, G-Jet Gastrojejunal Feeding Tube, Mic-Key® Secure-Lok® feeding devices, or other compatible enteral feeding devices. The extension set is for administering feeding, medications, and decompression to compatible devices.
Device Description:	The AMT Mini ONE® Enteral Extension Set is intended for use with the AMT Mini ONE® Gastrostomy Button, the AMT G-Jet Gastric-Jejunal Feeding Tube, Mic-Key® Secure-Lok® feeding devices, or other compatible feeding devices. The overall functionality and manufacturing methods remain similar to our original

	clearance of the Mini ONE Feeding Set in 510(K) K971757. The device materials and manufacturing methods were also recently cleared for use in our G-Jet Gastric-Jejunal Feeding Tube 510(K) Submissions K110804 and K123716. The main difference between our original Mini ONE Feeding Set Clearance (K971757) and this submission is the inclusion of new end connectors that are designed to the ISO/IEC 80369 series. The extension set consists of several different assembled components and materials that make up the device. Each extension set consists of several common components: A Mini ONE® connector that is able to connect to a compatible enteral feeding tube, flexible tubing, a pinch clamp to block the tubing, and ENfit enteral connector(s) to connect to a compatible feeding bag or syringe. There are two types of Mini ONE® connectors that are used for the extension set. The first type is a straight through connector that is used for bolus or gravity feedings/administration of medication. The second type of connector is a right angle connector that better directs the tubing around the patient for longer feedings/administration of medication. Both connectors are identical in material and in design along the connecting portion that fits with a compatible enteral device. The Mini ONE® connectors are also compatible with Kimberly Clark Mic-Key® Gastrostomy and enteral devices. Mic-Key® compatibility was cleared through the 510(K) process in K971757, K110804, and K123716. The flexible tubing used with each device comes in two different diameters and several different lengths. The two diameter options are provided to accommodate different types of feeds and medications to the patient. The tubing may be provided as straight tubing or in a coiled configuration. The different lengths are supplied to provide different options for patient orientation and maneuvering and include lengths of 2-24" lengths. Each tubing length also has a pinch clamp included to allow the user to close off the tubing while not in use. The enteral connectors in this submission are provided in two different configurations with the extension sets. The first configuration is a single ENFit connector assembled directly onto the tubing. The single port connection is typically used for bolus or gravity use. The second configuration is a Y-Port connection with two ENFit connections, each with a separate plug. The two port connection allows the user to administer medication and feed through the device at the same time.
Technological Characteristics:	The Mini ONE® Enteral Extension Set is provided non-sterile for single user use only. It is made from DEHP and Latex free materials. The Mini ONE® Enteral Extension Set is provided in a number of configurations providing different Mini ONE® adapter designs, lengths of tubing, diameters of tubing, and number of ENFit connectors. Description of each difference in design configurations is listed below: <u>Feeding Set Configurations:</u> • Type of Mini ONE® Connector: Straight (bolus/gravity) or right angle (continuous/pump) • Number of ENFit connectors: One or Two

	• Tubing Diameter: 0.218" or 0.165" • Tubing Length: 2-24" • Part Number Scheme: 8-XXXX (where XXXX signifies tubing length, number of ENFit connectors, MiniONE® Connector Type, and tubing diameter)
Biocompatibility Testing:	No additional Biocompatibility testing was performed for this submission. The device and materials in finished form for the Mini ONE® Enteral Extension Set were previously tested and cleared under 510(K) K123716 for permanent (greater than 30 days) skin contact.
Performance Testing:	AMT conducted various performance tests on all components contained within the Mini ONE® Enteral Extension Set. A human factors study was also conducted to ensure that the new enteral connectors do not affect usability and intended use of the device. The study found that usability and intended use of our enteral extension set is not affected by the new ENFit connectors. Bench tests have been carried out on samples of the AMT Mini ONE® Enteral Extension Sets with ENFit connectors. The tests carried out included: • Tensile strength • Fluid leakage • Stress cracking • Resistance to separation from axial load • Resistance to separation from unscrewing • Resistance to overriding • Disconnection from unscrewing • Flow testing Misconnection testing was conducted as recommended in the ISO 80369-1 standard. Connectors are made of rigid/semi rigid materials to reduce the risk of misconnection. Although the subject connector will not misconnect to other connectors in the 80369 series, misconnections with non ISO/IEC 80369 series connectors may still occur.
Conclusions:	The Mini ONE® Enteral Extension Set is substantially equivalent to the predicate device cleared under K971757 in intended use, patient population, design, biocompatibility and testing criteria, and method of operation.