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

May 28, 2015

Imed Technology, Inc.
Mr. Kyle Adams
President
2544 Tarpley Rd., Suite 112
Carrollton, Texas 75006

Re: K150513
Trade/Device Name: Imed Technology Intravascular Administration Sets and Imed Technology Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 28, 2015
Received: February 27, 2015

Dear Mr. Adams:

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 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. 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K150513

Device Name: IMed Technology Intravascular Administration Set and Imed Technology Extension sets

Indications For Use: IMed Technology Intravascular administration set and Imed Technology Extension sets intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. IMed Technology infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

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)

IMed Technology, LLC

Date Submitted:	May 1, 2015
Submitted By:	iMed Technology, Inc 2515 Tarpley Road, Suite 104 Carrollton, TX 75006 Tel: 972-732-7333 Contact email: kyle.adams@imedtechnology.com
Subject Device Name:	Imed Technology Intravascular Administration sets and Imed Technology Extension sets
Common Name of Device:	Intravascular Administration Set
Predicate Device:	Acta Medical Intravascular Administration Set (K121803)
Panel:	General Hospital and Personal Use
Product Code:	FPA
Device Classification:	21 CFR880.5440, Class II

Name & Model Numbers of Devices.

1. IMEDINF01, Intravascular administration set
2. IMEDINF02, Intravascular administration set with 0.2 micron filter
3. IMEDINF03, Intravascular administration set with flow regulator
4. IMEDINF04, Intravascular administration set with flow regulator, 0.2 micron filter
5. IMEDEXT01, Minibore extension set

Other Model Numbers and configurations may be assembled per customer request

Device Classification

a. Set, Administration, Intravascular
b. FPA
c. 21CFR880.5440
d. Device Classification II

Indications For Use

IMed Technology Intravascular administration sets and Imed Technology Extension sets intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features. IMed Technology infusion tubing may act as an extension of other infusion tubing in delivering intravenous fluids from a container to patient.

Device Description

IMed Technology, Intravascular administration/extension set is sterile, non-pyrogenic, non-DEHP PVC tubing with the following combination of components.

a. Universal Spike. Universal spike is constructed from ABS material and has a hydrophobic vent for transfer of fluids from closed containers such as infusion bottles. The spike dimensions are variable to deliver fluid at 10, 15, 20 and 60 drops per ml. Alternatively, the spike may have a luer lock at one end which connects to non-DEHP tubing for the purposes of transporting intravenous fluids from a vial to the patient.
b. Drip chamber with 15 micron filter. The drip chamber is constructed from non-DEHP PVC or EVA, is flexible and has inbuilt 15 micron particulate disc filter which filters solution passing through it.
c. Non-DEHP PVC tubing. Variable length non-DEHP PVC tubing with differing ID/OD combinations to ensure tubing performance. Extension tubing shall have ID/OD combinations of 0.03”/0.05” (minibore), 0.01”/0.03” (microbore), various lengths; 7” to 60”. Infusion tubing shall have ID of 0.1” and OD of 0.125”. Various combinations of the above tubing shall be designed to deliver desired performance.

d. Flow Regulator. A commercially available dial type flow regulator may be incorporated in-line to control the flow rate of infusion fluids. The flow regulator will provide standard graduations of 5ml/hr to a maximum of 250ml/hr. The flow regulator shall be constructed from medical grade ABS and medical grade silicone disc. Optionally, a rate restricted tubing may be also incorporated in the infusion set whereby the ID and length of the tubing has been calibrated to provide a specific flow rate at gravity pressure from liquid height of 36-40"
e. Roller clamp. A roller clamp may be inserted in combination with the above components to control flow rate or to turn fluid flow on and off. Roller clamp shall be constructed from medical grade ABS plastic
f. Slide clamp. A slide clamp may be inserted in combination with the above components to turn the fluid flow on and off. Slide clamp shall be constructed from medical grade ABS material.
g. Luer locks. Female luer locks and male luer locks may be a part of the infusion set as required and shall be constructed from medical grade ABS or non-DEHP hard PVC or medical grade PP.
h. Filters. In-line air eliminating filters may be incorporated into the infusion tubing. These filters will have pore size of 0.2 micron or 1.2 micron and shall be constructed from medical grade PVC or medical grade ABS and cellulose acetate membrane.
i. "Y" site (not made with natural rubber latex) or pre-approved needleless "Y" site for secondary infusions or medication administration. The "Y" site shall be integrated in combination with the above components and shall be constructed from hard PVC or PP or ABS (all components are medical grade). In case of an "injection port" (not made with natural rubber latex), the material shall be medical grade silicone.

Specification & Dimensions

IMed Technology, Intravascular Administration Set will have the following dimensional specifications:

a. Infusion tubing OD = 4.1mm, ID = 3.0mm (approximately)
b. Extension tubing regular bore OD = 2.7mm, ID = 1.6mm (approximately)
c. Extension tubing minibore OD = 2.0mm, ID = 1.0mm (approximately)
d. Extension tubing microbore OD = 1.6mm, ID = 0.6mm (approximately)
e. Additional custom dimensions may be manufactured for customers
f. Length may vary from 5" for extension set to 105" for primary infusion set

Materials

Acrylonitrile Butadiene Styrene
Non-DEHP Poly Vinyl Chloride
Polypropylene (non fluid pathway material, utilized in protective caps only)
Silicone

COMPARISON TABLE

IMed Technology Intravascular Administration Set Comparison To Acta Medical Intravascular Administration Set (K121803)

Feature	Details	Predicate Device K121803	Conclusion
Intended Use	IMed Technology, Intravascular Administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features.	Acta Medical Intravascular Administration set intended use is to deliver sterile, infusion fluid from a container to the patient with or without flow control features.	Substantially Equivalent
Design and Materials of Construction	The materials of construction for the proposed device are exactly the same as the materials for the predicate product	The design and materials of construction remain the same as the predicate product.	Substantially Equivalent
Labeling	Compliant with 21CFR807.87	Compliant with 21CFR807.87	Substantially Equivalent
Biocompatibility	Meets requirements for ISO 10993-1, External Communicating Device, Blood Path Indirect, Contact Duration A	Meets requirements for ISO 10993-1, External Communicating Device, Blood Path Indirect, Contact Duration A	Substantially Equivalent
Bench Testing	USP Physicochemical tests for plastics and performance testing compliant with ISO Standards	USP Physicochemical tests for plastics and performance testing compliant with ISO Standards	Substantially Equivalent
Sterilization	Sterility assurance level of 10^{-6}	Sterility assurance level of 10^{-6}	Substantially Equivalent

Labeling	As per Guidance Document	As per Guidance Document	Substantially Equivalent
ISO 8536-4:2010 tests for Intravascular Administration sets	Meets the acceptance criteria as specified in ISO 8536-4: 2010	Meets the acceptance criteria as specified in ISO 8536-4: 2010	Substantially Equivalent

Substantial Equivalence:

IMed Technology, Intravascular Administration Set is substantially equivalent to the predicate device, Acta Medical Intravascular Administration Set (K121803). The component materials, indication for use, SAL are substantially equivalent and present no additional concerns as compared to the predicate device.