January 11, 2019

International Medical Industries, Inc.
Kathleen Lavender
Director, Quality and Compliance
2981 Gateway Drive
Pompano Beach, Florida 33069

Re: K182545
Trade/Device Name: Tamper Evident Cap with Male Luer Lock
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: December 10, 2018
Received: December 12, 2018

Dear Kathleen Lavender:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182545

Device Name
Tamper Evident Cap with Male Luer Lock

Indications for Use *(Describe)*
The Tamper Evident Cap with Male Luer Lock is indicated for use as a cap for female Luer ports on medical devices such as manifolds, stopcocks or set.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary: K182545

Manufacturer:	International Medical Industries, Inc.
Address:	2981 Gateway Drive Pompano Beach, Florida 33069
Corresponding official:	Kathleen Lavender Director of Quality and Compliance
Telephone Number:	954.917.9570 x 283
Email:	klavender@imiweb.com

Summary Date:	January 10, 2019
Trade Name:	Tamper Evident Cap with Male Luer Lock
Common or Usual Name:	I.V. Administration Set
Regulation Number:	21 CFR 880.5440
Regulation Name:	Intravascular Administration Set
Product Code:	FPA
Class:	II
Panel:	General Hospital
Primary Predicate Device:	Dual Luer Lock Cap (K101385)
Secondary Predicate Device:	Tamper Evident Cap with Luer Lock (K861276)

Device Description:

The Tamper Evident Cap with Male Luer Lock (MTEC) is a sterile, single use device which will be used to cover female Luer ports on medical devices and provide evidence of access. MTEC is provided in two packaging configurations; a 10-up tray and single unit blisters. Both configurations are offered in multiple colors and all the components used in the manufacture of MTEC are comprised of polystyrene and polypropylene resin.

Indications for Use:

Feature of the device:	**Device:** K182545 Tamper Evident Cap with male Luer Lock	**Primary Predicate:** K101385 Baxter Dual Luer Lock Cap	**Secondary Predicate:** K861276 Tamper Evident Cap with Luer Lock	**Discussion/Comment** Device is pending premarket notification. Predicate is commercially available as Baxter Dual Luer Lock Cap Not subject to recall
Product Code	FPA	FPA	FPA	No Change
Classification	Class II	Class II	Class II	No Change
Number of uses	Single use Rx only	Single use Rx only	Single use Rx only	No Change
Materials	Device is an injection molded polypropylene component.	Device is an injection molded polypropylene component.	Device is an injection molded polypropylene component.	Same: No Change
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same: No Change
Biocompatibility	Biocompatibility assessment of the Dual Luer Lock Cap has been conducted based on ISO 10993-1 - Biological Evaluation of Medical Devices.	Biocompatibility assessment of the Dual Luer Lock Cap has been conducted based on ISO 10993-1 - Biological Evaluation of Medical Devices.	Biocompatibility assessment of the Dual Luer Lock Cap has been conducted based on ISO 10993-1 - Biological Evaluation of Medical Devices.	Same: No Change
Indication for Use:	The Tamper Evident Cap with Male Luer Lock is indicated for use as a cap for female Luer ports on medical devices such as manifolds, stopcocks or sets.	The Dual Luer Lock Cap is indicated for use as a cap for male or female Luer ports on medical devices such as manifolds, stopcocks or sets.	The Tamper Evident Cap with Female Luer Lock is indicated for use as a cap for male Luer ports on medical devices	The primary difference is that the primary predicate device has both male and female Luer connection points whereas the proposed device only has a male Luer lock connection point. The primary difference between the secondary predicate device and the proposed device is that the secondary predicate only has a female Luer lock connection point.
Design Feature: Tamper Evidence	Device is designed to cover an open Luer port after the Luer port has been accessed and will provide evidence of tampering if removed after installation.	Device is designed to cover an open Luer port after the Luer port has been accessed.	Device is designed to cover an open Luer port after the Luer port has been accessed and will provide evidence of tampering if removed after installation.	The proposed product is designed with a primary function of a standard male Luer lock cap with a secondary function as a tamper evident (evidence of access)

Technological Characteristics:

The MTEC device is an assembly of injection molded components with a polypropylene Luer lock tip cap. The intended use and function of the proposed device is identical to the primary predicate device with respect to functionality. Both the proposed device (tip cap) and the primary predicate device are comprised of polypropylene resin. There are two design differences between the proposed device and the primary predicate device. The primary difference is that the primary predicate device has both male and female Luer connection points whereas the proposed device only has a male Luer lock connection point. The second difference is that the proposed device has a tamper evident design feature. This design feature is identical to the secondary predicate device.

Performance Data:

Bench testing was performed to demonstrate that the proposed MTEC device is substantially equivalent to both the primary predicate and secondary predicate devices.

Test Name	Test Description
ISO 80369-7:2016	Design verification to ISO 80369-7:2016 *Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications*
Shelf Life Evaluation	Design verification of the shelf life.
Sterilization Product Adoption	AAMI TIR 28:2009/(R)2013 *Product adoption and process equivalence for ethylene oxide sterilization*
Packaging	ISO 11607-1:2006 *Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems*
Sterility	ISO 11135:2014 *Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*
Residuals	ISO 10993-7:2008 *Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals*
Biocompatibility	ISO 10993-1, *"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff, Jun 16, 2016 and "Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)]," July 11, 2008, as recognized by the FDA.*

Discussion of Non-Clinical Testing:

International Medical Industries conducts risk analyses and design verification tests that are based on the result of these analyses. All test results meet the acceptance criteria and support that the device is appropriately designed for the intended use.
The MTEC device meets the bench testing requirements of ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications. The primary predicate device was tested to ISO 594-2:1998 which has since been replaced by ISO 80369-7:2016.
Compliance with ISO 80369-7:2016 demonstrates that The MTEC device meets the Bench performance testing requirements as follows:

* Separation Force

* Unscrewing torque

* Ease of assembly * Stress cracking

* Liquid leakage test

* Resistance to overriding

Proposed device vs. primary predicate device

The MTEC device meets the bench testing requirements of ISO 80369-7:2016 *Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications*. The primary predicate device was tested to ISO 594-2:1998 which has since been replaced by ISO 80369-7:2016. Compliance with ISO 80369-7:2016 demonstrates that the proposed device is substantially equivalent to the primary predicate device K101385.

Proposed device vs. secondary predicate device

The MTEC device's tamper evident design feature was tested and successfully passed all internal specifications. It is substantially equivalent to the secondary predicate device K861276.

Biocompatibility Testing

Biocompatibility testing of the Tamper Evident Cap with Male Luer Lock was conducted per Guidance Document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"; Guidance for Industry and Food and Drug Administration Staff, Jun 16, 2016 and "Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)]," July 11, 2008, as recognized by the FDA. Biocompatibility testing was conducted in accordance with the cited guidance and standards as required for an External Communicating Device, Blood Path, Indirect Contact, Limited Duration.

Conclusion:

Review of the in-vitro performance test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility demonstrate that the subject device, Tamper Evident Cap with Male Luer Lock (MTEC) is substantially equivalent to the primary predicate device, the Baxter Dual Luer Lock Cap (K101385). Any technological differences between the subject and the predicate devices do not raise any issues of safety and effectiveness.