January 31, 2020

International Medical Industries Inc.
David Meily
Director of Quality & Regulatory Affairs
2981 Gateway Drive
Pompano Beach, Florida 33069

Re: K193192
Trade/Device Name: Tamper Evident Cap
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 7, 2019
Received: January 8, 2019

Dear David Meily:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K193192

Device Name
Prep-LockTM Tamper Evident Cap for IV Syringes

Indications for Use *(Describe)*
Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.

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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K193192 510(k) Summary

Date Summary Prepared:	November 15, 2019
Manufacturing Company:	International Medical Industries, Inc.
Manufacturing Address:	2981 Gateway Drive, Pompano Beach, Florida 33069
Corresponding Official:	David Meily Director of Quality and Regulatory Affairs
Telephone Number:	954.917.9570 x 283
Fax Number:	954.917.9244
Email Address:	dmeily@imiweb.com
Trade Name:	Prep-Lock™ Tamper Evident Cap for IV Syringes
Device 510(k):	K193192
Device Common Name:	Tamper Evident Cap
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston syringe
Product Class:	II
Product Panel:	General Hospital
Product Code:	FMF
Predicate Device Name:	Prep-Lock™ Tamper Evident Cap for IV Syringes (Originally cleared as Tamper Proof Cap)
Predicate Device 510(k):	K861276 cleared May 5, 1986
Device Common Name:	Tamper Evident Cap
Regulation Number:	21 CFR 880.5860
Regulation Name:	Piston syringe
Product Class:	II
Product Panel:	General Hospital
Product Code:	FMF

1. Device Description

The Tamper Evident Cap (TEC) is a sterile, single use device which will be used to cover male luer ports on medical devices and provide evidence of access. TEC is offered in multiple colors and all the components used in the device are comprised of polystyrene and polypropylene resin. The TEC device is marketed as a stand-alone device and packaged in bulk.

2. Indications for Use

Subject Device IFU: TEC in Bulk Bags	Predicate Device IFU TEC in Individual Trays and Blister Packs
Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.	Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.

Discussion of differences in indications for use

The Indications For Use remains the same.

3. Comparison of Technological Characteristics and Basis for Substantial Equivalence

Table 5.3.1 – Comparison Between Subject and Predicate Devices

Parameter	Subject Device	Predicate Device	Comparison
Proprietary Device Name	Prep-Lock™ Tamper Evident Cap for IV Syringes	Prep-Lock™ Tamper Evident Cap for IV Syringes	Same
Packaging Configuration	Pouches that contain 100 TEC units.	Individual blister packs and 10-up trays.	The packaging configuration has been tested and conforms to the same functional and sterility specifications as the predicate device. The cap itself is unchanged.
Labeling	Instructions on how to open 100 cap packaging	Instructions on how to open 10 cap packaging	Labeling has been slightly modified on how to open the new packaging
Sterility	Sterile EO (10^-6)	Sterile EO (10^-6)	Same
Number of Uses	Single Use, Rx only	Single Use, Rx only	Same
Cap Material	Polypropylene / Polystyrene	Polypropylene / Polystyrene	Same
Shelf Life	3 years	3 years	Same

Tamper Evidence Design Feature	Cap separation upon opening	Cap separation upon opening	Same
Biocompatibility Contact / Duration	Indirect blood contact, limited duration.	Indirect blood contact, limited duration.	Same

Discussion of Technological differences

The device is a tamper evident cap used to cover male luer ports on medical devices and provide evidence of access. The device is marketed as a stand-alone device and packaged in bulk. Both the subject device and the predicate device are comprised of the same resin and are manufactured by the same injection molding / assembly process. There are no changes in the cap from the currently marketed predicate device and the subject device. The update is in the packaging configuration in which the caps are provided. The subject device is provided in a new packaging configuration; a carton containing 10 pouches where each pouch contains 100 TEC units. The predicate device was offered in 10-up trays and single unit blisters. The instructions for use have been updated to provide slight modifications to the instructions on how to open the new packaging.

The safety and effectiveness of the proposed TEC device is adequately supported by the material information, comparison of design characteristics with the predicate device, testing rationale and data summarized within this premarket notification. This testing supports the equivalence of the TEC in bulk packaging to the predicate TEC device and shows that no new questions of safety and effectiveness have been introduced with the packaging modification.

4. Non-Clinical Bench Testing

The new packaging configuration was assessed and the following performance testing was conducted. Packaging design verification and validation were performed to ensure that the subject TEC device in bulk packaging meets the existing functional specifications and demonstrates equivalence to the predicate device packaging. A summary of the testing conducted is presented below. All pre-determined acceptance criteria were met. The data demonstrates that the subject device is substantially equivalent to the predicate device.

Table 5.4.1 – Summary of Performance Testing Conducted on Subject Device

Test Name	Test Description
Sterility Assurance 10^{-6} SAL	Sterilization product adoption for Tamper evident cap in Tyvek Pouch (Bulk Bag) conducted per ANSI/AAMI/ ISO 11737-2: 2009/(R)2014 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
Sterilization Product Adoption	AAMI TIR 28 Product adoption and process equivalence for ethylene oxide sterilization

Shelf Life	ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices1
EO/ECH Residuals	ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Device Function	AAMI ANSI HE75 Human factors engineering—Design of medical devices ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications – Connectors for intravascular or hypodermic applications Tamper Evident Break Force Test Method (IMI Internal) Simulated Use Test Method (IMI Internal) Weld Strength (IMI Internal)
Packaging Integrity	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection (ASTM F 1886) Minimum Peel Strength (ASTM F 88)
Transportation	ISTA 3B TEST Over 150 lbs. Pallet Test, Visual on Seal per ASTM F1886, Dye Penetration per F1929,
Product Validation	Human factors and Usability, limited to assessment of packaging use.

Biocompatibility Testing

The packaging material for the subject and predicate devices have no patient contact. Biocompatibility testing of the TEC device 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.

5. Clinical Bench Testing

Not applicable for this change.

6. Conclusion

Review of the performance test summaries 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 in the bulk bag configuration is substantially equivalent to the predicate Tamper Evident Cap in single and 10-up packaging configurations. The difference between the subject and the predicate devices do not raise any new questions of safety or effectiveness.