September 4, 2024

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

Re: K231095
Trade/Device Name: Tamper Evident Cap
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 2, 2024
Received: August 5, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231095

Device Name
Tamper Evident Cap

Indications for Use *(Describe)*
Tamper Evident Caps (Sterile) 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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510(k) Summary
Tamper Evident Caps K231095

1. Submission Sponsor

International Medical Industries, Inc.
2981 Gateway Drive.
Pompano Beach
FL, 33069 USA
Contact: David Meily
Title: VP Quality & Regulatory Affairs

2. Submission Correspondent

Not applicable

3. Date Prepared

30 August 2024

4. Device Identification

Trade/Proprietary Name:	Tamper Evident Cap
Common/Usual Name:	syringe, piston
Classification Name:	syringe, piston
Regulation Number:	21 CFR 880.5860
Product Code:	FMF
Device Class:	Class II
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

Predicate Device:	Tamper Evident Cap
510(k) Number:	K861276
Common/Usual Name:	syringe, piston
Classification Name:	syringe, piston
Regulation Number:	21 CFR 880.5860
Product Code:	FMF
Device Class:	Class II
Classification Panel:	General Hospital

6. Indication for Use Statement

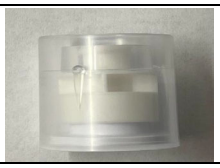
Tamper Evident Caps (Sterile) are indicated for use as a sterile tamper evident cap for IV syringes.

7. Device Description

The International Medical Industries, Inc. Tamper Evident Cap consists of a polystyrene outer sleeve and bottom cover and a polypropylene tip cap held in place by a breakaway ring integrated into the sleeve. Evidence of access to the Luer lock cap is achieved by physically breaking the connection and removing the polystyrene outer sleeve exposing the Luer lock cap. Removal of the Luer Lock Cap is restricted by the presence of the sleeve. The restrictive sleeve and cap are available in multiple colors (cosmetic purposes only) in individual blister packs and trays of 10. The Luer Lock Caps are provided sterile to the end user. The sterilization method used is Ethylene Oxide.

8. Substantial Equivalence Discussion

Parameter	Subject Device	Predicate Device	Substantial Equivalence Determination
510(k)	K230195	K861276	N/A
Company Name	International Medical Industries, Inc.	International Medical Industries, Inc.	N/A
Status	Pending 510(k) review	Commercially available	N/A
Indications for Use	Tamper Evident Caps (Sterile) are indicated for use as a sterile tamper evident cap for IV syringes.	Tamper Evident Caps (Sterile) are indicated for use as a sterile tamper evident cap for IV syringes.	Same as Predicate Device
Classification	Class II	Class II	Same as Predicate Device
Regulation Number	880.5860	880.5860	Same as Predicate Device
Product Code	FMF	FMF	Same as Predicate Device
Number of Uses	Single use, Rx only	Single use, Rx only	Same as Predicate Device
Material (sleeve and bottom cap)	Polystyrene	Polystyrene	Same as Predicate Device
Material (tip cap)	ExxonMobil™ PP9074MED Polypropylene Random Copolymer	LyondellBasell Pro-fax 6523 Polypropylene Homopolymer	Subject Device differs from Predicate Device, but same as Reference Device (K193192). Overall, no impact on Safety and Equivalence
Biocompatibility	Limited	Limited	Same as Predicate Device
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same as Predicate Device
Shelf Life / Expiration	3 years	3 years	Same as Predicate Device
Electrical, chemical, thermal, radiation safety, anatomical site, energy used/delivered	Not applicable	Not applicable	N/A
Applicable Test Standards	ISO 80369-7	ISO 80369-7	Same as Predicate Device

Parameter	Subject Device	Predicate Device	Substantial Equivalence Determination
Visual Comparison			Same as Predicate Device

A comparison of the Subject Device (K230195) to the currently marketed Predicate Device (K861276) indicates the following similarities:

- Intended Use / Indications for use
- Operating Principle
- Mechanism of action
- Performance
- Shelf Life
- Sterilization process and requirements
- Packaging configuration and materials
- Material for the Sleeve and Bottom Cap

When compared to the Predicate Device (K861276), the Tamper Evident Caps (K230195), the Subject Device, has the following difference:

- Material used for Tip Cap [(Subject Device: ExxonMobil™ PP9074MED Polypropylene Random Copolymer) and (Predicate Device: LyondellBasell Pro-fax 6523 Polypropylene Homopolymer)

The material difference is addressed through the comparison to the Reference Device , the Tamper Evident Cap (K193192), which utilizes the same material as the Subject Device.

The safety and effectiveness of the TEC Subject Device are supported by the testing rationale and data provided, materials information, and comparison of design characteristics as found in the comparison table above. The testing provided supports the substantial equivalence of the Tamper Evident Cap Subject Device proposed material from that of the Predicate Device and poses no new questions of safety and effectiveness, including shelf life, when compared to the predicate device. No new hazards or risks were identified as a result of the material change. The Subject Device's material remains biocompatible as evidenced in the testing.

9. Non-Clinical Performance Data

The testing was conducted as part of the Design Control process for the TEC product family to keep current with the latest ISO standard, 80369. For this product line, the applicable standards are ISO 80369-7:2016, "Small-bore connectors for liquids and gases in healthcare applications – Part 7 Connectors for intravascular or hypodermic applications", and ISO 80369-20:2015 "Common test methods".

The acceptance criteria stipulated in the design verification protocol for the TEC product family, which was based on ISO 80369-7:2016 and ISO 80369-20:2015 have been met. TEC passes ISO 80369 testing and associated standards and is therefore considered verified.

Additionally, the Tamper Evident Caps have undergone a complete set of biocompatibility testing:

- ASTM Hemolysis Study - Extract Method [(ASTM) F756-17 ISO 10993-4:2017, ISO 10993-12:2021]
- Cytotoxicity Study Using the ISO Elution Method [ISO 10993-5:2009, ISO 10993-12:2021, ISO 10993-1:2018]
- Infrared Spectroscopy [ISO 10993-18:2020 / A1:2022]
- ISO Acute Systemic Toxicity Study [ISO 10993-1:2018, ISO 10993-11:2017]
- ISO Guinea Pig Maximization Sensitization Test [ISO 10993-10:2021]
- ISO Intracutaneous Irritation Study – Extract [ISO 10993-23:2021]
- Microscopic Particle Count Test [USP 788]
- Particulate Analysis - Device - Light Obscuration Method [USP 788]
- USP Rabbit Pyrogen Study Material Mediated [ISO 10993-11:2017]

Tamper Evident Caps have undergone nonclinical testing to support their substantial equivalence to the predicate device. Tamper Evident Caps have passed the required testing. Material differences between the subject device and the predicate device are the same as our company's cleared reference device K193192. There are no additional safety or effectiveness differences between the subject and the predicate devices. Therefore, the Tamper Evident Caps are substantially equivalent to the legally marketed predicate device K861276.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use are equivalent to the predicate device.

11. Conclusion

In summary, the Tamper Evident Cap (K231095) is substantially equivalent to the predicate device, Tamper Evident Caps cleared through K861276, in that it has the same intended use, Indications for Use, and sterilization method, and it meets the same test standard (ISO 80369-7). Where there are differences in materials used in the tip cap for the subject device versus the predicate device, the materials used for the subject device are the same as our company's cleared reference device K193192. Overall, the Tamper Evident Cap (K231095) does not raise any new questions of safety or effectiveness when compared to the predicate device, and the data presented supports a determination of Substantial Equivalence.