April 30, 2019

International Medical Industries, Inc.
Peter Lehel
Senior Manager Engineering
2981 Gateway Drive
Pompano Beach, Florida 33069

Re: K190305
Trade/Device Name: Additive Cap
Regulation Number: 21 CFR 880.5025
Regulation Name: IV Container
Regulatory Class: Class II
Product Code: KPE
Dated: February 7, 2019
Received: February 12, 2019

Dear Peter Lehel:

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,

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)*
K190305

Device Name
Additive Port Cap

Indications for Use *(Describe)*
The Additive Port Cap is indicated for use on the medication port of Baxter VIAFLEX, Baxter INTRAVIA, Baxter AVIVA, and Baxter ALL-IN-ONE EVA containers to provide both visual evidence that medication has been added and tamper evidence once the device is closed.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K190305 510(k) Summary

Date Summary Prepared:	February 7, 2019
Manufacturing Company:	International Medical Industries, Inc.
Manufacturing Address:	2981 Gateway Drive, Pompano Beach, Florida 33069
Corresponding Official:	Peter Lehel Senior Manager Engineering
Telephone Number:	954.917.9570 x 227
Fax Number:	954.917.9244
Email Address:	plehel@imiweb.com
Trade Name:	Additive Port Cap
Device Common Name:	Additive Cap
Regulation Number:	21 CFR 880.5025
Regulation Name:	I.V. Container
Product Class:	II
Product Panel:	General Hospital
Product Code:	KPE
Predicate Device:	Baxter Additive Cap for Viaflex Containers K111217 cleared June 14, 2011

5.1 Device Description

The Additive Port Cap (APC) is a polypropylene, single use device designed to snap over the outside of the medication port of compatible Baxter IV container (Baxter VIAFLEX, Baxter INTRAVIA, Baxter AVIVA, and Baxter ALL-IN-ONE EVA) after the addition of medication. Once closed, the device prevents the port from being accessed without causing visible damage to the IV container. The bright red coloration serves as a clear indicator that medication has been added. The APC device is non-fluid path and non-sterile. The APC device is marketed as a stand-alone device and packaged in bulk.

5.2 Indications for Use

Device: Additive Port Cap (APC)	Predicate: Baxter Additive Cap for Viaflex Containers K111217
The Additive Port Cap is indicated for use on the medication port of Baxter VIAFLEX, Baxter INTRAVIA, Baxter AVIVA, and Baxter ALL-IN-ONE EVA containers to provide both visual evidence that medication has been added and tamper evidence once the device is closed.	Additive Cap is indicated for use on the medication port of VIAFLEX and AVIVA containers to provide visual evidence that medication has been added.

5.3 Technological Characteristics and Basis for Substantial Equivalence

The APC is substantially equivalent to the predicate device, Baxter Additive Cap for VIAFLEX and AVIVA Containers (K111217)**.** The devices are both indicated as non-fluid path caps which provide visual evidence that medication has been added to the specified IV containers. Both devices are injection molded polypropylene and are provided non-sterile.

Table 5.3.1 – Comparison Between APC and Predicate Devices

Parameter	Proposed Device	Predicate Device
Image	 Injection port fit.  Installed.	 Injection port fit.  Installed.
Proprietary Device Name	Additive Port Cap (APC)	Additive Cap for Viaflex Containers
Company Name	International Medical Industries, Inc.	Baxter Healthcare Corporation
510(k) #	K190305	K111217
Product Code	KPE	KPE
Regulation No.	21 CFR 880.5025	21 CFR 880.5025
Classification	Class II	Class II
Sterility	Non-Sterile	Non-Sterile
Number of Uses	Single Use	Single Use
Cap Material	Polypropylene	Polypropylene
Biocompatibility Contact and Duration	Device does not contact the patient's body directly or indirectly.	Device does not contact the patient's body directly or indirectly.

The label modification is to expand the indications for use statement by adding compatibility with the Baxter INTRAVIVA and Baxter ALL-IN-ONE EVA containers which are functionally equivalent to the VIAFLEX and AVIVA. The second label modification is to add tamper evidence to the indications for use. Performance testing to demonstrate tamper evidence was conducted. Once the Additive Port Cap is attached and closed, it cannot be opened manually. If a closed cap is opened (e.g. with a tool), it can cause damage to the bag or the cap making it unusable. Additionally, performance testing demonstrated that pulling on the cap in order to remove from the bag tears the bag.

Table 5.3.2 – Differences Between APC and Predicate Devices

Feature of the Device	Proposed Device	Predicate Device	Discussion / Comment
Compatibility with Baxter fluid containers.	Baxter VIAFLEX, Baxter INTRAVIA, Baxter AVIVA, and Baxter ALL-IN-ONE EVA containers	VIAFLEX and AVIVA containers	The medication port are equivalent for all the containers.
Tamper Evidence	Includes tamper evidence	Does not include tamper evidence.	Performance testing was conducted to support claim of tamper evidence.

The safety and effectiveness of the APC are adequately supported by the material information, comparison of design characteristics with the predicate device, testing rationale and data provided within this premarket notification. This testing supports the substantial equivalence of the APC to the predicate and shows that no different questions of safety and effectiveness have been introduced with this device.

5.4 Performance Data

Design verification and validation were performed to ensure that the APC device meets its performance specifications and demonstrates substantial equivalence to the predicate device. There are no known performance standards for this device. A summary of the performance testing conducted is presented below. All pre-determined acceptance criteria were met. The data demonstrates that the proposed cap device is substantially equivalent to the predicate device.

Table 5.4.1 – Summary of Performance Testing Conducted on APC Device

Test Name	Test Description
Visual Inspection	Visual Inspection to ensure no gross damage, coverage of drug port etc.
Axial Detachment	Force required to remove the additive port cap from IV container
Opening Force	Force required to open a properly installed cap
Closing Force	Force required to properly install product on injection port of IV container
Dimensional Verification	Dimensional measurements of cap features
Leakage	Drug port freedom from leakage

Packaging and Labeling	Visual inspections to verify integrity of the packaging to protect the device and of the label to be legible.
Transportation, Shelf Life	Simulated transportation conditions and shelf life followed by design verification testing.
Product Validation	Human factors and Usability

5.5 Biocompatibility Testing

The device does not contact the patient's body either direct or indirectly. In accordance to FDA 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" issued June 16, 2016, no biocompatibility testing is required for the APC device.

Conclusion

Review of the 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, Additive Port Cap (APC) is substantially equivalent to the predicate cap Baxter Additive Cap for VIAFLEX and AVIVA Baxter containers K111217. Any differences between the subject and the predicate devices do not raise any different questions of safety or effectiveness.