October 6, 2017

International Medical Industries, Inc.
Brandon Hunt
Vice President Operations
2981 Gateway Drive
Pompano Beach, FL 33069

Re: K170672
Trade/Device Name: Tamper Evident Cap For use with ENFit® Syringes
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PNR
Dated: October 2, 2017
Received: October 3, 2017

Dear Brandon Hunt:

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 Industry and Consumer Education (DICE) 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" (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 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 Industry and Consumer Education (DICE) 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170672

Device Name
Tamper Evident Cap For use with ENFit® Syringes

Indications for Use *(Describe)*
Tamper Evident Cap For use with ENFit® Syringes is indicated for use to prevent fluid loss and contamination of syringe contents until ready for use with evidence of access.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5 - 510(k) Summary

Date Prepared:	October 5, 2017
Company:	International Medical Industries, Inc.
Contact:	Brandon Hunt Vice President Operations International Medical Industries, Inc. 2981 Gateway Drive Pompano Beach, Florida 33069 Phone 954.917.9570 Ext. 229 Fax 954.917.9244
Trade Name:	Tamper Evident Cap For use with ENFit® Syringes
Device Common Name:	ENFit Syringe Cap
Classification Regulation:	21 CFR 876.5980
Classification Name:	Gastrointestinal Tube and accessories
Class:	II
Panel:	Gastroenterology/Urology
Product Code:	PNR
Predicate Device:	International Medical Industries, Inc. Tamper Proof Cap with Luer Lock (K861276)
Reference Device:	NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps (K152857)

5.1 Device Description

Tamper Evident Cap For use with ENFit® Syringes is a sterile, single use disposable device for use as a closure cap with evidence of access for Enteral Syringes with ENFit™ Connectors. Removal of the cap is achieved by removing a restrictive sleeve covering the ENFit™ Lock Cap. A damaged or missing restrictive sleeve indicates potential tampering. A non-sterile version of the device is also offered.

5.2 Indications for use

Tamper Evident Cap For use with ENFit® Syringes is indicated for use to prevent fluid loss and contamination of syringe contents until ready for use with evidence of access.

5.3 Comparison of Technological Characteristics

The Tamper Evident Cap For use with ENFit® Syringes is an assembly of injection molded components with a polystyrene outer sleeve and bottom cover and acrylic Syringe Tip Cap. The intended use and function of the proposed Tamper Evident Cap For use with ENFit® Syringes is identical to the predicate device in design and operation. The primary difference between the proposed device and the predicate device is that the predicate device contains a female Luer lock with tamper evident features on the outer sleeve, whereas the proposed device contains a male ENFit® connector for use with a ENFit® syringe, with tamper evident features integrated into the cap.

The intended use and function of the proposed Tamper Evident Cap For use with ENFit® Syringes is identical to the reference device in design and operation. The primary difference between the proposed device and the reference device is that the proposed product contains evidence of access features also known as Tamper Evidence.

International Medical Industries, Inc

Parameter	Proposed Device	Predicate Device	Reference Device
Image	 (Multiple Colors)		
Proprietary Device Name	Tamper Evident Cap For use with ENFit® Syringes	Tamper Proof Cap with Luer Lock	NeoMed NeoConnect™ Enteral Syringes with ENFit™ Connector and compatible NeoSecure™ Tip Caps
Company Name	International Medical Industries, Inc.	International Medical Industries, Inc.	NeoMed, Inc.
510(k) #	K170672	K861276	K152857
Indications For Use	Tamper Evident Cap For use with ENFit® Syringes is indicated for use to prevent fluid loss and contamination of syringe contents until ready for use with evidence of access.	Tamper Proof Caps provide Evidence of Use and Positive Closure for Luer Lock Syringes	A NeoConnect ™ Enteral Syringe Accessory used to prevent fluid loss and contamination of syringe contents until ready for use
Product Code	PNR	FMF	PNR
Regulation No.	21 CFR 876.5980	21 CFR 880.5860	21 CFR 876.5980
Classification	Class II	Class II	Class II
Sterilization Method	Ethylene Oxide (for sterile versions)	Ethylene Oxide	Ethylene Oxide
Number of Uses	Single Use, RX Only	Single Use, RX Only	Single Use, RX Only
Closure Cap Material	Acrylic	Polypropylene	Polypropylene
Biocompatibility	Per ISO 10993-1 for prolonged duration, surface device, mucosal membrane	Unknown	Unknown
Connection	Male ENFit	Female Luer Lock	Male ENFit

5.4 Performance Data

The Tamper Evident Cap For use with ENFit® Syringes meets the bench testing requirements per "AAMI/ISO 80369-3: Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications" for the following tests:

- Liquid Leakage
- Stress Cracking
- Resistance to Separation from Axial Load
- Resistance to Separation from Unscrewing
- Resistance to Overriding
- Disconnection by Unscrewing

Additional performance bench tests were performed to verify that the Tamper Evident Cap For use with ENFit® Syringes meets internal specifications. The main performance data provided in support of the substantial equivalence determination included:

- Visual Indication of Tamper Evidence during Simulated Misuse Conditions
- Durability and Performance of Tamper Evidence during Installation and Removal
- Durability and Performance of Tamper Evidence during Simulated Misuse Conditions
- Compatibility with Use Environments during Simulated Installation and Removal
- Ease of Use / Human Factors of Tamper Evident Caps
- Impact on Dose Accuracy of Syringe

Compliance to AAMI/ISO 80369-3 and additional internal specifications, demonstrates that the proposed cap device is substantially equivalent to the predicate device.

5.5 Biocompatibility Testing

The device, Tamper Evident Cap For use with ENFit® Syringes, passed all biocompatibility tests. In accordance to 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," June 16, 2016, the following biocompatibility tests were performed: Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Material-Mediated Pyrogen Testing, and Acute/Subacute Systemic ToxicityThe device is considered a device with mucosal membrane contact of prolonged duration.

5.6 Conclusions:

Tamper Evident Cap For use with ENFit® Syringes is substantially equivalent to the predicate device (Tamper Proof Cap, K861276),. The devices have the same intended use, the sterilized versions are sterilized with acceptable methods, and the performance testing supports substantial equivalence in device performance.