October 20, 2022

Emed Technologies Corporation
Olena Whalen
QA/RA/CA Manager
1262 Hawks Flight Ct, Ste. 200
El Dorado Hills, California 95762

Re: K213429
Trade/Device Name: AccuSert Needle Inserter
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: Class II
Product Code: KZH
Dated: September 6, 2022
Received: September 13, 2022

Dear Olena Whalen:

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,

CAPT Alan M. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213429

Device Name
AccuSert Needle Inserter

Indications for Use *(Describe)*
AccuSert Needle Inserter is intended for use at home or hospital environment to assist inserting EMED subcutaneous administration needle sets into the subcutaneous tissue at 90 degrees. Single patient use only.

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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K213429 510(k) Summary

Date Prepared: October 20, 2022

I. SUBMITTER

EMED Technologies Corporation
1262 Hawks Flight Ct
El Dorado Hills, CA 95762

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II. DEVICE

Trade Name: AccuSert Needle Inserter
Common or Usual Name: Introducer, Syringe Needle
Classification Name: Syringe needle introducer
Regulation Number: 21 CFR §880.6920
Product Code: KZH

III. PREDICATE DEVICE

(K010377), Sil-Serter Inserter (Product Code – KZH)

IV. DEVICE DESCRIPTION

The EMED AccuSert Needle Inserter is a manually operated, reusable, spring-loaded injection device. This device is used to insert EMED subcutaneous infusion administration sets. The device is contraindicated for use with other sets. The AccuSert Needle Inserter consists of a plastic body containing a stainless-steel spring and a needle carrier component.

The user places and securely seats the infusion set onto the carrier. The administration set is then loaded and locked into the AccuSert by pushing the needle carrier handle (thereby compressing the internal spring) until the carrier clicks/locks into place. The AccuSert is placed in contact with the intended insertion site and activated to release the infusion set at a 90° angle. The spring drives the carrier and the infusion set needle is inserted into the users' subcutaneous tissue.

V. INTENDED USE/INDICATIONS FOR USE:

AccuSert Needle Inserter is intended for use at home or hospital environment to assist inserting EMED subcutaneous administration needle sets into the subcutaneous tissue at 90 degrees. Single patient use only.

VI. TECHNOLOGICAL COMPARISON WITH PREDICATE DEVICE

The AccuSert Needle Inserter is not based on new technology, nor is it based on new clinical application of an existing technology. The device is based on well-established technology that has existed for decades; any advances or improvements are the result of incremental change of the existing technology in which design enhancements were enacted in an effort to improve safety, appearance, and usability, as well as to allow for physical compatibility with proprietary EMED administration set design characteristics and performance requirements.

Table 5-1: Comparison of Technological Characteristics with Predicates

Parameter	Sil-Serter Inserter (K010377)	EMED Accusert Needle Inserter	Comparison
Indications for Use	The Silserter infusion set insertion system is intended as an aid for insertion of the Silhouette family of infusion sets. Single patient use only.	AccuSert Needle Inserter is intended for use at home or hospital environment to assist inserting EMED subcutaneous administration needle sets into the subcutaneous tissue at 90 degrees. Single patient use only.	Insignificant difference (See NOTE 1 below).
Prescription or Over the Counter	Prescription	Prescription	SAME
Environment of Use	Home use	Home and Hospital Use	Insignificant difference (see NOTE 2 below)
Material(s)	**Housing:** ABS Plastic **Carrier:** Nylon **Barrel:** ABS Plastic **Springs:** 302 Stainless Steel **Release buttons:** Nylon **Damper ring:** Thermoplastic Elastomer (TPE) **Trigger button:** Polycarbonate **Bonding Solvent:** Cyclohexanone	**Housing:** Polycarbonate **Needle Carrier:** Delrin **Springs**: 304 Stainless Steel **Release button:** ABS Plastic	Insignificant difference (see NOTE 3 below)
Dimensions (l x h x d) and Weight	Approximately 6.75in x 1.43in x 1.43in Weight not specified.	1.65in x 1.41in x 4.03in 36.6 grams (0.08 lbs.)	Insignificant difference (see NOTE 4 below)
Principle of Action	Manually Operated	Manually Operated	SAME
Pressure Source	Spring-loaded	Spring-loaded	SAME
Safety Feature(s)	Device release button locking mechanism to prevent accidental discharge. Carrier tabs to maintain traveling distance of 1.69in. and insertion distance.	Recessed released button mechanism to prevent accidental discharge. Carrier stop to maintain traveling distance of 1.19in.	Insignificant difference (see NOTE 5 below)
Device Performance	Designed to withstand 600 cycles	Designed to withstand 550 cycles	Insignificant difference (see NOTE 6 below)
Cocking Force	Less than 7 lbf	9-7 lbf	Insignificant difference (see NOTE 7 below)
Trigger/Release Force	Less than 7 lbf	Less than 7 lbf	SAME

Parameter	Sil-Serter Inserter (K010377)	EMED Accusert Needle Inserter	Comparison
Insertion Force	1.67 lbf	1.0 -2.5 lbf	Insignificant difference (see NOTE 8 below)
Biocompatibility	Not applicable. The device does not come into direct contact with blood or body fluids. Momentary limited skin contact.	The battery of testing included: • Chemical Characterization • Cytotoxicity • Sensitization • Skin Irritation	Insignificant difference (see NOTE 9 below)
Sterility	Non-Sterile	Non-Sterile	SAME
Validated Cleaning Method	Manual	Manual	SAME
Usable Life	1 year	1 year	SAME

NOTE 1: The Indications for Use statement for the AccuSert Needle Inserter are not identical to the predicate device. However, the differences do not affect the intended use of the device, nor does it affect the safety and effectiveness of the device relative to the predicate. Both devices are intended to aid in the insertion of specific infusion sets. Both the predicate and subject AccuSert Needle Inserter are indicated for single patient, multi-use. The insertion of the needle into subcutaneous tissue at 90 degrees is achieved through the design of the needle of the infusion set and not the design of the AccuSert Needle Inserter.

NOTE 2: The use of AccuSert Needle Inserter in the hospital or home environment does not have any impact on the safety or effectiveness of the device as there is no special training needed to use the device. The conducted Human Factors Validation Testing serve as objective evidence that the instructions for use provide the user with sufficient information to understand how the device is used.

NOTE 3: There are no bonding solvents or glues used in AccuSert Needle Inserter. The materials that compose the AccuSert Inserter were identified for their durability and performance characteristics. The plastics selected are widely used for medical device applications.
The slight differences in the materials do not raise any new safety or effectiveness questions. The performance testing (biocompatibility and design verification) conducted on AccuSert Needle Inserter demonstrates the device functions as intended.

NOTE 4: The devices' form factor is different in design for the specific needle sets. The size and/or weight difference does not impact portability, usability, safety or the intended function, as both devices can insert the corresponding needle set into the skin.

NOTE 5: Both devices are designed to prevent accidental discharge. The minor difference in traveling distance do not have an impact to safety, performance, or effectiveness as both devices were designed and tested to insert the specific infusion needle sets into the skin. The AccuSert was designed with an adequate traveling distance to insert the intended needle set while maintaining small form factor design.

NOTE 6: The specified usable life for the AccuSert Needle Inserter and predicate are very similar: 550 cycles and 600 cycles, respectively. This is a minor difference that does not indicate any reasonable difference in technology, performance, or safety of the devices. The number of

simulated uses for the AccuSert Needle Inserter includes data derived from testing of multiple Inserters as well as performance testing to validate expected usable life duration.

NOTE 7: The predicate and subject devices operate in the same operational principle – the user must load the infusion set into the device, compress a spring and activate the device by pressing a trigger button. The force needed to load the AccuSert Needle Inserter and activate the release trigger were validated as appropriate though Usability Validation that demonstrated that the intended users could use the device safely and effectively without user errors or difficulties that could cause harm.

NOTE 8: The predicate and subject devices operate in the same operational principle – the user must load the infusion set into the device, compress a spring and activate the device by pressing a trigger button. With the subject device (AccuSert Needle Inserter) the needles are inserted into the skin using slightly lower spring force than the predicate device. However, the slight difference in spring force does not have a safety or effectiveness impact. The AccuSert was designed with adequate force to insert the intended needle sets with the minimum force and impact to the patient skin as confirmed by conducted performance testing

NOTE 9: The AccuSert Needle Inserter has been evaluated for biocompatibility and is acceptable for its intended use by Biological Evaluation

VII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

No clinical study is included in this submission.

The following performance data were provided in support of the substantial equivalence determinations:

Biocompatibility

The biocompatibility evaluation was conducted in accordance with the international standard EN ISO 10993-1 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within A Risk Management Process” as recognized by FDA. The battery of testing included the following:

- Chemical Characterization (ISO 10993-18:2020 Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process)
- Cytotoxicity (ISO 10993-5:2009 Biological evaluation of medical devices – Part 5 testing for in vitro cytotoxicity)
- Sensitization (ISO 10993-10:2021 Biological evaluation of medica devices – Part 10 tests for skin sensitization)
- Skin Irritation (ISO 10993-23:2021 Biological evaluation of medical devices – Part 23 tests for irritation)

The AccuSert Needle Inserter has been evaluated for biocompatibility and is acceptable for its intended use by Biological Evaluation.

Design Verification

Various performance tests were conducted to provide objective evidence that the device retains its mechanical properties and functions with EMED subcutaneous administration needle sets which include:

- Cocking Force
- Trigger Force
- Insertion Force
- Visual/Functional
- Life Cycle testing
- Chemical Resistance
- Drop Test
- Cleaning
- Usability Evaluation

The aforementioned tests were completed compliant with the following standards:

- ANSI/AAMI HE75:2009 (R2018) Human Factors Engineering - Design of Medical Devices
- IEC 62366-1:2015 Medical devices part 1, Application of usability engineering to medical devices
- ISO 28620:2020 Medical devices – Non-electrically driven portable infusion devices (Standard used to perform the Drop Test)

Results from performance testing indicate that the product meets the established performance requirements.

VIII. FINAL CONCLUSION:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K010377.