September 26, 2024

Promisemed Hangzhou Meditech Co., Ltd.
% John Beasley
Founding Member and Senior Consultant
MedTech Review, LLC
257 Garnet Garden Street
Henderson, Nevada 89015

Re: K242632
Trade/Device Name: Verifine® Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 3, 2024
Received: September 3, 2024

Dear John Beasley:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242632

Device Name
Verifine® Pen Needles

Indications for Use *(Describe)*
Verifine® Pen Needle is intended for use with pen injector device for the subcutaneous injection of drugs.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K242632 510(k) Summary

Verifine® Pen Needles

1. Submission Sponsor

Promisemed Hangzhou Meditech Co., Ltd.

No. 1388 Cangxing Street Cangqian Community, Yuhang District Hangzhou City Zhejiang 311121 China

Contact: Mr. Zearou Yang

Office Phone: +8657188772985

Email: jim@nemoto-do.co.jp

2. Submission Correspondent

MedTech Review, LLC

257 Garnet Garden Street Henderson NV 89015 United States

Contact: John Beasley

Office Phone: +7027236889

Email:john@medtechreview.com

3. Date Prepared

September 03, 2024

4. Device Identification

Trade/Proprietary Name:	Verifine® Pen Needles
Classification Name:	Needle, Hypodermic, Single Lumen
Regulation Number(s):	880.5570
Product Code(s):	FMI
Class:	II
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

Device name: Verifine ® Common Type Insulin Pen Needle and Verifine® Safety Type Insulin Pen Needle

510(k) number: K161950

Manufacturer: Promisemed Hangzhou Meditech Co., Ltd.

6. Device Description

Verifine® Pen Needles, manufactured by Promisemed Hangzhou Meditech Co., Ltd, are designed for use with pen injectors for the administration of drugs. These are standard pen needles without integrated safety features. The devices are single-use, non-pyrogenic, and maintain a Sterility Assurance Level (SAL) of 10^{-6}. The differences between the PromiseMed current cleared common type needle pen and the new design primarily involve changes to the trade name, the addition of new models, and modifications in some materials and dimensions. Key updates include a change in the trade name, the introduction of new models (FPN and NPN), the addition of new needle sizes and a 5-bevel needle tip option, and a shift from a specific intended use (administering insulin) to a general intended use (administering drugs). The materials used have also been slightly modified, such as changing the needle shield material from polypropylene (PP) to polyethylene (PE) for certain models, which only contact intact skin, ensuring no increased risk. These devices are intended for over-the-counter (OTC) use and require manual insertion by the user during drug administration.

7. Indication for Use Statement

Verifine® Pen Needle is intended for use with pen injector device for the subcutaneous injection of drugs.

8. Substantial Equivalence Discussion

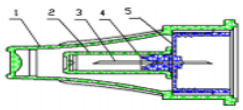
The following table compares the Verifine® Pen Needles to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

SE Comparison

This table provides a detailed comparison of the modified device against the cleared device, ensuring that no new concerns regarding safety or effectiveness have been introduced by the changes.

Item of description	Cleared device	Modified device		Comments on Similarities/Differences	Safety/Effectiveness Statement
Common name	Insulin Pen Needles	No change		N/A	No new concerns. The common name remains unchanged, ensuring consistency with the intended use.
Trade name	Verifine® Common Type Insulin Pen Needle	IPN	Verifine® Pen Needles	It is only for common type pen needle. Only the trade name is change.	No new concerns. The trade name change does not impact safety or effectiveness as the device's function remains the same.
		FPN, NPN	Verifine® Plus Pen Needles		
Classification name	Needle, Hypodermic, Single Lumen (21 CFR 880.5570)	No change		N/A	No new concerns. The classification name remains consistent.
Device class	Class II	No change		N/A	No new concerns. The device remains in Class II, indicating no change in risk level.
Product Code	FMI	No change		N/A	No new concerns. The product code remains the same, reflecting no change in device functionality.
General description	The proposed product, insulin pen needle, is manufactured by Promisemed Hangzhou Meditech Co., Ltd, which is designed for use with a pen injector for the subcutaneous injection of insulin. The products have two types, common type and safety type. Both of the two types are sterile with a Sterility Assurance Level (SAL) of 10-6, non-pyrogenic and single-use devices. Each type has several models. Different models are distinguished by needle gauge and length. The Common Type Insulin Pen Needle consists of needle container, needle shield, needle tube, needle hub, UV glue	The proposed product, Verifine® Pen Needles, is manufactured by Promisemed Hangzhou Meditech Co., Ltd, which is designed for use with a pen injector for the subcutaneous injection of insulin. The product is common type without safety protective feature. It is a sterile with a Sterility Assurance Level (SAL) of 10^{-6}, non-pyrogenic and single-use devices. Each type has several models. Different models are distinguished by needle gauge and length. It is consisting of needle container, needle shield, needle tube, needle hub, UV glue and silicone oil. UV glue is used		It is only for common type pen needle. Description about common type is no change.	No new concerns. The change to a broader intended use does not introduce new risks as the fundamental technology and operation remain the same.

Item of description	Cleared device	Modified device	Comments on Similarities/Differences	Safety/Effectiveness Statement
	and silicone oil. UV glue is used to glue needle tube and needle hub and the silicone oil is used to needle tube lubrication. The user proceeds with inserting the needle into the skin manually. Both the Common Type Insulin Pen Needle and the Safety Type Pen Needle are for OTC use, and they are external communication, blood indirect devices. The contact duration for both subjected devices is within 24h, and they belong to limited contact device according ISO 10993-1.	to glue needle tube and needle hub and the silicone oil is used to needle tube lubrication. The user proceeds with inserting the needle into the skin manually. It is intended for OTC use, and they are external communication, blood indirect devices. The contact duration for both subjected devices is within 24h, and they belong to limited contact device according ISO 10993-1.		
Principles of operation	The user proceeds with inserting the needle into the skin manually. The patient end and the cartridge end of the tube are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.	No change	N/A	No new concerns. The principles of operation remain unchanged, ensuring consistent performance.
Indication of use	The Common Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	Verifine® Pen Needle is intended for use with pen injector device for the subcutaneous injection of drugs.	Change in the trade name and from specific use (insulin) to general use (drugs).	No new concerns. The broader indication for use does not introduce new safety or effectiveness risks as the device's mechanism remains unchanged.
Model	IPN-29-12, IPN-30-8, IPN-31-4, IPN-31-5, IPN-31-6, IPN-31-8, IPN-32-4, IPN-32-5, IPN-32-8, IPN-33-4	Model / Specification code IPN / Not defined. FPN / Not defined. NPN / Not defined.	New two models of FPN and NPN were added. Specification code was not defined that the needle was identified through by metric size.	No new concerns. The addition of new models and sizes expands options without altering the device's safety or effectiveness.
Needle size	IPN 0.33mm×12mm, 0.30mm×8mm, 0.25mm×4mm, 0.25mm×5mm, 0.25mm×6mm, 0.25mm×8mm, 0.23mm×4mm, 0.23mm×5mm, 0.23mm×8mm, 0.20mm× 4mm,	IPN, FPN, NPN 0.33mm×12mm, 0.30mm×8mm, 0.25mm×4mm, 0.25mm×5mm, 0.25mm×6mm, 0.25mm×8mm, 0.23mm×4mm, 0.23mm×5mm, 0.23mm×6mm, 0.23mm×8mm, 0.20mm× 3.5mm, 0.20mm× 4mm, 0.20mm× 5mm, 0.18mm× 3.5mm, 0.18mm× 4mm, 0.18mm× 5mm,	Some size was added.	No new concerns. The addition of new needle sizes does not impact safety or effectiveness; the new sizes comply with standard specifications.

Item of description		Cleared device	Modified device	Comments on Similarities/Differences	Safety/Effectiveness Statement
Bevel		3	Bevel / Model / Needle size 3 bevels / IPN, FPN, NPN / All sizes 5 bevels / IPN, FPN, NPN / All sizes	Bevel of needle tip is defined. Addition of 5 bevel design.	No new concerns. The introduction of a 5-bevel design is intended to enhance user experience without affecting safety or effectiveness.
Dimension	Needle Gauge	29G, 30G, 31G, 32G, 33G	29G, 30G, 31G, 32G, 33G, 34G	Outer diameter of 34G (0.18mm) was added, per K210059.	No new concerns. The added dimensions meet regulatory standards, ensuring safety and effectiveness.
	Length	4mm, 5mm, 6mm, 8mm, 12mm	3.5mm, 4mm, 5mm, 6mm, 8mm, 12mm	Nominal length of 3.5mm was added.	
Color			Not defined.	There is no color designated to each size that metric size is identified through the gauge and length, and there is no color requirement for pen needle in ISO 11608-2.	No new concerns. The lack of a defined color does not impact the safety or effectiveness of the device.
Schematic diagram and picture		IPN  **Fig. 1—Schematic representation of IPN** **Key** 1 Needle container 4 Jointing medium 2 Needle shield 5 Needle hub 3 Needle tube	No change	There is only the difference about shape of needle shield and hub for each model.	No new concerns. The design variations do not introduce new safety or effectiveness risks, as they are minor adjustments to the device's form.

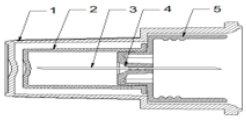
<table>
<tr><th>Item of description</th><th>Cleared device</th><th>Modified device</th><th>Comments on Similarities/Differences</th><th>Safety/Effectiveness Statement</th></tr>
<tr><td></td><td>/</td><td>FPN
 

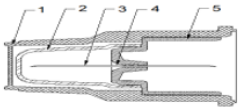
Fig. 2—Schematic representation of FPN
Key
1 Needle container 4 Jointing medium
2 Needle shield 5 Needle hub
3 Needle tube</td><td></td><td></td></tr>
<tr><td></td><td>/</td><td>NPN
 

Fig. 3—Schematic representation of NPN
Key
1 Needle container 4 Jointing medium
2 Needle shield 5 Needle hub
3 Needle tube</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Item of description</th><th>Cleared device</th><th>Modified device</th><th>Comments on Similarities/Differences</th><th>Safety/Effectiveness Statement</th></tr>
<tr><td>Product picture</td><td>/</td><td> 
Side view
 
Front view</td><td>There is only the difference about shape of needle shield and hub for each model.</td><td>No new concerns. The design variations do not introduce new safety or effectiveness risks, as they are minor adjustments to the device's form.</td></tr>
<tr><td>Material</td><td>IPN
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<table><tr><th>Component</th><th>Material</th></tr><tr><td>Needle tube</td><td>Stainless steel (X5CrNi18-10)</td></tr></table></td><td>Material of needle shield is changed to PE which is only contact intact skin.</td><td></td></tr>
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Item of description		Cleared device	Modified device	Comments on Similarities/Differences	Safety/Effectiveness Statement
			Needle Shield: Polyethylene (PE) Needle Container: Polypropylene (PP) Needle Hub: Polypropylene (PP) Glue (Joint medium): UV Glue Lubricant: Silicone oil Dialyzing paper (Seal): Medical grade glue dialyzing paper		
		/	NPN Needle tube: Stainless steel (X5CrNi18-10) Needle Shield: Polypropylene (PP) Needle Container: Polypropylene (PP) Needle Hub: Polypropylene (PP) Glue (Joint medium): UV Glue Lubricant: Silicone oil Dialyzing paper (Seal): Medical grade glue dialyzing paper	No change.	
Performance requirements		Remain no change	No change	N/A	No new concerns. Performance requirements remain unchanged, ensuring consistent functionality.
Labeling	Unit package	Remain no change	No change	N/A	No new concerns. Labeling updates meet current standards and enhance the device's safety and usability.
	User package	Remain no change	Blow contents were changed: 1. Indication; 2. warning; 3. direction for use; 4. compatible pens;	These changes are meeting for requirement of ISO 11608-2:2022.	
	Instruction for use	Remain no change	Blow contents were changed: 1. Indication; 2. warning; 3. direction for use;	These changes are to be met for requirement of ISO 11608-2:2022.	

Item of description		Cleared device	Modified device	Comments on Similarities/Differences	Safety/Effectiveness Statement
			Needle Shield: Polyethylene (PE) Needle Container: Polypropylene (PP) Needle Hub: Polypropylene (PP) Glue (Joint medium): UV Glue Lubricant: Silicone oil Dialyzing paper (Seal): Medical grade glue dialyzing paper		
		/	NPN Needle tube: Stainless steel (X5CrNi18-10) Needle Shield: Polypropylene (PP) Needle Container: Polypropylene (PP) Needle Hub: Polypropylene (PP) Glue (Joint medium): UV Glue Lubricant: Silicone oil Dialyzing paper (Seal): Medical grade glue dialyzing paper	No change.	
Performance requirements		Remain no change	No change	N/A	No new concerns. Performance requirements remain unchanged, ensuring consistent functionality.
Labeling	Unit package	Remain no change	No change	N/A	No new concerns. Labeling updates meet current standards and enhance the device's safety and usability.
	User package	Remain no change	Blow contents were changed: 1. Indication; 2. warning; 3. direction for use; 4. compatible pens;	These changes are meeting for requirement of ISO 11608-2:2022.	
	Instruction for use	Remain no change	Blow contents were changed: 1. Indication; 2. warning; 3. direction for use;	These changes are to be met for requirement of ISO 11608-2:2022.	

The following changes were identified between the subject and predicate devices:

- **Trade Name:** Changes in the subject device trade name from the predicate does not raise new or different questions of safety and effectiveness as the device's functions remains the same.

- **Indications for Use:** The broadened indications for use in the subject device trade name from the predicate does not raise new or different questions of safety and effectiveness as the device's principle of operation remains the same.
- **Introduction of FPN and NPN Models and Needle Sizes (dimensions, bevel):** The addition of new models and sizes expands options without altering the device's safety or effectiveness when compared to the predicate device. Additionally, the new needle sizes comply with standard specifications. Finally, unlike with the insulin needle in the predicate device, the subject device uses metric size instead of color, as there is no color requirement for pen needles in ISO 11608-2.
- **Material:** The material of the subject device (IPN and FPN) needle shield has been changed to polyethylene (PE) from polypropylene (PP), which only contacts the skin. Biocompatibility testing was performed in accordance with ISO 10993 to support this change and does not raise new or different questions of safety and effectiveness.
- **Labeling:** Subject device indications for use, warnings, directions for use, and compatible pens have been updated. This does not raise new or different questions of safety and effectiveness, as they are based on results/ review from the points identified above. That is, the device's functions remain the same.

9. Non-Clinical Performance Data

To support substantial equivalence to the predicate device, Promisemed Hangzhou Meditech Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.

Verification and Validation Activities - Design Changes:
Needle Sizes: Additional sizes ranging from 0.33mm×12mm to 0.18mm×3.5mm were introduced to meet clinical needs, focusing on reducing outer diameter for increased patient comfort and ensuring safety by minimizing the risk of intramuscular injections.

Compatible Pens: The pen needle compatibility was expanded to include additional pen models, such as ClikSTAR®, SoloSTAR®, and FlexTouch®, to address the evolving market and clinical requirements.

Needle Shield Material: The needle shield material was changed from Polypropylene (PP) to Polyethylene (PE) to improve manufacturing efficiency. The new material was tested and found to be biocompatible and non-toxic as per ISO 10993-1.

Testing Performed:
Labeling and Dimensional Compliance: Visual inspections were conducted on unit packaging to ensure metric size labeling compliance with ISO 11608-2. The needle's dimensions, including the container, shield, and hub, were measured, and found to comply with drawing requirements.

Performance Testing: The pen needles underwent performance testing (reports VR-20230818-02 and VR-20210528-03) to assess dose accuracy and needle removal torque. The testing confirmed that the needles meet the performance criteria outlined in ISO 11608-2.

Biocompatibility Testing: The new Polyethylene (PE) material for the needle shield was tested for cytotoxicity, skin irritation, intracutaneous reactivity, and sensitization according to ISO 10993-1 standards. The results confirmed that the material is non-toxic and safe for use in its intended application.

Test Results:
All verification and validation tests passed without deviations, confirming that the Verifine® Pen Needles meet the necessary design specifications and regulatory requirements. The tests demonstrated that the product modifications did not introduce any new risks related to safety or effectiveness when compared to the predicate device.

Conclusions:
Based on the results of the non-clinical verification and validation activities, it can be concluded that the modified Verifine® Pen Needles are substantially equivalent to the predicate device K161950. The changes, including the addition of new needle sizes, compatible pens, and the material change of the needle shield, have been thoroughly evaluated and verified to meet all applicable performance and safety standards. Therefore, the device is as safe and effective as the predicate device for its intended use, and no new risks have been introduced.

10. Clinical Performance Data

No clinical data was necessary to determine the substantial equivalence of this device.

11. Statement of Substantial Equivalence

The Verifine® Pen Needles have the same indications for use as the predicate devices listed above. Any minor differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, the Verifine® Pen Needles have been determined to be substantially equivalent to the predicate device.