



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

June 9, 2015

Ypsomed AG  
c/o Mr. Lee Leichter  
P/L Biomedical  
10882 Stonington Avenue  
Fort Myers, FL 33913

Re: K150662

Trade/Device Name: Clickfine Pen Needle and Penfine Classic Pen Needle  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: II  
Product Code: FMI  
Dated: May 7, 2015  
Received: May 11, 2015

Dear Mr. Leichter:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150662

Device Name

Clickfine Pen Needle and Penfine Classic Pen Needle

Indications for Use (Describe)

The pen needles are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

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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K150662

## 8. 510(k) Summary

Submitted By/

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Date Prepared:

May 07, 2015

- 8.1 Trade/Proprietary Name: Clickfine Pen Needle  
Penfine Classic Pen Needle
- 8.2 Common/Usual Name: Injection Pen Needle
- 8.3 Classification Name: Hypodermic single lumen needle
- 8.4 Classification: FDA has classified Hypodermic single lumen needles in Class II according to 21 CFR 880.5570. Final Order was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification Panel.
- Panel: 80                      Procode: FMI
- 8.5 Predicate Device: K131125 Clickfine Pen Needles
- 8.6 Purpose of Submission: To add a second product line of needles (Penfine Classic Pen Needles) that are attached to pens by using only a “classic” screwing or twisting action in addition to the existing Clickfine Pen Needle line that can also be “clicked” or “snapped” onto the pen. The submission also includes other minor changes to both product lines, including the addition of needle point geometry with 6-bevels (in addition to the existing 3-bevel geometry), changes to the needle hub, labeling and sterilization cycle.

## 8.7 Device Description

All of the subject device pen needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of prescribed fluids. Each needle is individually packaged in a sealed protective container with a peel tab. The subject device pen needles are used by peeling back the peel tab. The hub of the currently marketed Clickfine Pen Needle is snapping or screwing onto the threaded end of the pen injector. The modified Penfine Classic Pen Needle is attached to pen injectors with only a “screwing” motion. For all needles the back end of the cannula punctures the rubber injection port of the drug reservoir in the pen-injector. The outer protective cap is then removed. The inner protective cap will remain over the needle until the fluid is ready to be injected. When the injection is needed, the inner protective cap is removed and the needle is inserted into the chosen site. The pen-injector automatically delivers the fluid through the needle. The protective cap is replaced and the needle is then unscrewed for the pen injector, discarded and replaced with a new needle before the next injection.

## 8.8 Intended Use

The intended use of the modified device remains the same as the predicate device - Clickfine Pen Needles (K131125):

The pen needles are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.

## 8.9 Technological Characteristics and Substantial Equivalence Discussion

The technological characteristics have not changed. All of the materials, processes and operating principles of the modified needles are identical to the currently marketed needles. The Penfine Classic Pen Needle has a modified interface to only allow attachment to compatible cartridge holders through a twisting or screwing motion, while the current device can be snapped, or “clicked” onto the cartridge holder. The only other change is a different grinding of the needle point to produce six, rather than three surfaces. Otherwise the needles have the same design and intended use as the currently marketed product and are compatible with the same injection pens. As such, the subject needles are substantially equivalent to the predicate Clickfine Pen Needles (K131125).

## 8.10 Performance Data

As part of the Design Control Activities, Ypsomed evaluated the potential risks, hazards or hazardous situations, potential clinical impact on the patient, identified the appropriate risk control measure and acceptability criteria associated with each change in the modified devices. Then, each risk was mitigated through appropriate verification and/or validation activities which were determined to be the testing specified in the following international and internal standards and protocols. This testing confirmed that the subject devices are substantially equivalent to the predicate devices.

All Subject Device Pen Needles have met the requirements of the relevant sections of the following standards:

- ISO 11608-2:2012 Needle based injection systems for medical use –

Requirements and test methods – Part 2: Needles

- ISO 9626:1991/Amd.1:2001 Stainless steel needle tubing for the manufacture of medical devices
- ISO 7864:1993 Sterile hypodermic needles for single use

<b>Test</b>	<b>Section of Standard</b>
Needle assembly attachment shall fit and function with needle based injection systems specified in ISO 11608-1	Clause 4.2.1 of ISO 11608-2 The subject device pen needles were tested on compatibility with needle based injection system as specified in ISO 11608-1
Tubing dimensions	Clause 4.2.2, Table 1 of ISO 11608-2 Length of patient end: +/- 1.25 mm Length of cartridge end: 5.7 – 7.0 mm
Flow rate	Clause 4.3 of ISO 11608-2: Measurement of flow rate in accordance with Annex A.
Bond between hub and needle tube	Clause 9 of ISO 11608-2 and clause 13.1 of ISO 7864 The union of the hub and needle tube shall not break for at least 5 sec. while a force of at least 22 N is applied
Needle points	Clause 4.5 of ISO 11608-2 Visually sharp at a 2.5x magnification; designed to minimize coring and fragmentation
Lubrication	Clause 4.7 of ISO 11608-2 No visible droplets on the outside surface of the needle tube.
Dislocation of measuring point at the patient-end	Clause 8 of ISO 11608-2: 4, 6, 8, 10mm +/- 0.9mm, 12mm +/- 1.1mm
Functional compatibility with needle based injection systems	Clause 11 of ISO 11608-2: Needle assembly torque: 0.07 +/- 0.01 Nm Needle hub removal: less than 0.100 Nm Dose accuracy: for doses ≤ 20 ml the calculated values were within ± 0.01 ml of the targeted dose; for doses > 20 ml the calculated values were within ± 5 % of the targeted dose.
Tubing characteristics	Table 1 of ISO 9626/A1: The tubing is made of austenitic stainless steel acc. one of the designated types given in Table 1 of ISO 9626/A1.
Tubing diameters	Table 2 of ISO 9626/A1

Test	Section of Standard
	Tubing dimensions meet outer and inner diameter requirement as defined in table 2 of ISO 9626/A1.
Stiffness	Clause 9 of ISO 9626: When tested in accordance with annex C of ISO 9626 the tubing shall show a deflection not greater than the relevant value given in table 3 of ISO 9626/A1.
Resistance to breakage	Clause 10 of ISO 9626: When tested in accordance with annex D of ISO 9626 and Table 4 if ISO 9626/A1 the tubing shall not break.
Limits for acidity and alkalinity	Clause 6 of ISO 9626 Tested in accordance with annex A and extract preparation of the tubing in accordance with Annex B: correction for the volume of titrant required for the control fluid shall not be more than 0.04 ml NaOH or 0.12 ml HCl to reach the end-point titration.
Resistance to corrosion	Clause 11 of ISO 9626: When tested in accordance with annex E, the immersed half of the tubing shall show no evidence of corrosion resulting from the test.
Patency of lumen	Clause 13.2 of ISO 7864 A stylet, having a diameter equivalent to 80% $\pm$ 2% of lumen inner diameter must pass through freely
Freedom of defects	Clause 11.3 in ISO 7864: When examined by normal or corrected-to-normal vision, the needle shall appear straight and of regular cross-section and wall thickness
Limits for extractable metals	Clause 6 of ISO 7864: When tested with a recognized method the content of lead, tin, zinc and iron shall be less than 5mg/l. The cadmium content shall be lower than 0.1 mg/l.
Freedom of defects	Clause 11.3 of ISO 7864: When examined by normal or corrected vision, the needle lube shall appear straight and of regular cross-section and wall thickness.

The verifications have shown evidence that the subject device pen needles meet the acceptance criteria of these standards. Based on the results it can be concluded that the device performance is acceptable for the product.

#### 8.11 Conclusion

Ypsomed AG concludes based on the information presented that the modified products are substantially equivalent to the current product (Clickfine Pen Needles) legally marketed in the USA.