



Food and Drug Administration
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November 18, 2015

Ypsomed AG
Mr. Stephan Affolter
Head of Quality System & Regulatory Affairs
Brunnmattstrasse 6, CH- 3401 Burgdorf
SWITZERLAND

Re: K152514

Trade/Device Name: Clickfine AutoProtect Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: II
Product Code: FMI
Dated: October 20, 2015
Received: October 22, 2015

Dear Mr. Affolter:

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 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 Industry and Consumer Education 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

Enclosure

Indications for Use

510(k) Number (if known)

K152514

Device Name

Clickfine AutoProtect Pen Needle

Indications for Use (Describe)

The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

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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8 510(k) Summary for K152514

Submitted By/
Contact Person:

Stephan Affolter
Head of Quality System & Regulatory Affairs
Ypsomed AG
Brunnmattstrasse 6
CH - 3401 Burgdorf
Switzerland
Tel. 0041-34 424 3382
Fax 0041-34 424 4122
E-mail: stephan.affolter@ypsomed.com

Alternative Contact:

Lee Leichter
President
P/L Biomedical
10882 Stonington Avenue
Fort Myers, FL 33913
USA
Tel. (239) 244-1448
Fax. (815) 550-0162
E-mail: leichter@plbiomedical.com

Date Prepared:

September 23, 2015

8.1 Trade/Proprietary Name:

Clickfine AutoProtect Pen Needle

8.2 Common/Usual Name:

Injection Pen Needle

8.3 Classification Name:

Hypodermic single lumen needle

8.4 Classification: Regulation 21 CFR Part 880.5570 - Hypodermic single lumen needle was published in the Federal Register on October 21, 1980 after review by the General Hospital and Personal Use Devices Classification, classifying *Hypodermic single lumen needles* in Class II.

Panel: 80

Procode: FMI

8.5 Predicate Device: K131123 Clickfine AutoProtect Pen Needle

8.6 Purpose of Submission: To widen the range of the needle lengths and include a 5 mm Clickfine AutoProtect pen needle.

8.7 Device Description

The pen needles are sterile, non-pyrogenic, single use needles designed to be used with commercially available pen-injectors for the administration of fluids. Each needle is individually packaged in a sealed protective container with a peel tab.

The pen needle is used by peeling back the peel tab and snapping or screwing the housing onto the threaded end of the pen-injector. The back end of the cannula punctures the septum of the drug reservoir in the pen-injector. The outer protective cap is then removed. When the injection is needed the needle is inserted into the chosen site. While inserting the needle into the skin, the safety shield glides into the housing enabling the needle to penetrate the skin barrier and the subcutaneous tissue. While the safety shield glides into the housing the safety mechanism is activated. The pen-injector delivers the medicinal product through the needle.

After the injection, in order to remove the needle from the skin, the user withdraws the pen injector from the skin. As the pen and needle is withdrawn from the skin, the safety shield glides back in its initial position, completely covering the needle, where it will remain locked. The safety shield is designed to automatically cover the needle (providing passive protection) to minimize the risk of accidental needle-stick injury. Once the Clickfine AutoProtect Pen Needle is in the locked mode, it can no longer be used. The red safety lock indicator tells the user that the safety lock has been activated. The needle is detached from the injection device and disposed of in accordance with local regulations. For each subsequent injection, another disposable needle must be used.

8.8 Intended Use

The intended use of the modified device remains the same as the predicate device Clickfine AutoProtect Pen Needles K131123:

The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin and exenatide.

Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.

8.9 Technological Characteristics and Substantial Equivalence discussion

For the 5 mm Clickfine AutoProtect, except for the material of the needle shield, all of the material, processes and operating principles are identical to the currently marketed pen needles.

Comparison to Predicate Device

Characteristic	Current Ypsomed Clickfine AutoProtect Injection Pen Needle 8 and 6 mm	Modified Ypsomed Clickfine AutoProtect Injection Pen Needle 5 mm
510(k)	K131123	N/A
Indications for use	The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	Unchanged
OTC	OTC	Unchanged
Needle length	6 and 8 mm	5, 6 and 8 mm
Needle gauge	31, 30 and 29 gauge	Unchanged
Needle outer diameter	0.25, 0.3 and 0.33 mm	Unchanged
Needle inner diameter	Normal walled needle: ≥ 0.114, ≥ 0.133 and ≥ 0.133 mm	Unchanged
	Thin walled needle: ≥ 0.125, 0.165 and ≥ 0.190 mm	Unchanged
Needle grind	Front and back bevel	Unchanged
Needle tip:	3-bevel	Unchanged
Method of attachment to pen	"Snap-on" & "Twist-on" attachment and Twist-off removal	Unchanged
Needle material	Stainless steel	Unchanged
Needle/hub bond	Adhesive bonded	Unchanged
Hub material	PP	Unchanged
Housing	White colored PP	Unchanged
Needle shield	Blue colored MBS, using the Zylar 530 granulate	Blue colored MBS, using the Zylar 550 granulate
Safety lock indicator	Red colored PP	Unchanged
Spring	Stainless steel	Unchanged

Characteristic	Current Ypsomed Clickfine AutoProtect Injection Pen Needle 8 and 6 mm	Modified Ypsomed Clickfine AutoProtect Injection Pen Needle 5 mm
Outer protective container material	Blue colored PP	Unchanged
Peel tab	PET	Unchanged
Sterilization method	Gamma irradiation	Unchanged
Sterilization conditions	25 kGy	17.5 kGy
IFU	Leaflet	Unchanged

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.

The Clickfine AutoProtect 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
- ISO 23908:2011 Sharps injury protection – Requirements and test methods

Test	Requirement	Result
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 pen needles were tested for compatibility with needle based injection system as specified in ISO 11608-1	Pass
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	Pass

Test	Requirement	Result
Flow rate	Clause 4.3 of ISO 11608-2: Measurement of flow rate in accordance with Annex A.	Pass
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	Pass
Needle points	Clause 4.5 of ISO 11608-2 Visually sharp at a 2.5x magnification; designed to minimize coring and fragmentation	Pass
Lubrication	Clause 4.7 of ISO 11608-2 No visible droplets on the outside surface of the needle tube.	Pass
Dislocation of measuring point at the patient-end	Clause 8 of ISO 11608-2: maximum allowable dislocation acc. Clause 4.8, Table 2 for 5mm: 0.65mm and for 8mm: 0.9mm	Pass
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 \leq 20 ml the calculated values were within \pm 0.01 ml of the targeted dose; for doses $>$ 20 ml the calculated values were within \pm 5 % of the targeted dose.	Pass
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.	Pass
Tubing diameters	Table 2 of ISO 9626/A1 Tubing dimensions meet outer and inner diameter requirements as defined in table 2 of ISO 9626/A1.	Pass
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.	Pass
Resistance to breakage	Clause 10 of ISO 9626: When tested in accordance with annex D of ISO 9626 and Table 4 of ISO 9626/A1 the tubing shall not break.	Pass

Test	Requirement	Result
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.	Pass
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.	Pass
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	Pass
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.	Pass
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.	Pass
Activation of the sharps injury protection	In accordance with ISO 23908 clause 5.2 the sharps injury protection feature shall be able to be activated by an appropriate force that eases actuation and avoids unintended actuation. An appropriate force was determined using a risk-based approach in accordance with ISO 14971.	Pass
Verification of safety feature activation	In accordance with ISO 23908, clause 5.3, needles were tested to provide evidence that once the safety feature was activated, they resist axial and lateral forces so as to prevent unintended exposure to the sharps.	Pass
Device design verification for needle tip protection after activation	In accordance to clause 5.4 of ISO 23908 it was demonstrated that a sphere of 6mm radius did not come into contact with the tip of the cannula, either before or immediately after triggering the safety mechanism.	Pass

The 5 mm Clickfine AutoProtect Pen Needles were tested, and met all meet all acceptance criteria, for all the requirements as provided above. Based on the results Ypsomed concluded that the device performance is acceptable for the product.

8.11 Clinical Data

Clinical Data was not required to establish substantial equivalence for these devices.

8.12 Conclusion

Ypsomed AG concludes based on the information presented that the subject device is substantially equivalent to the predicate product legally marketed in the USA.