510(k) Summary - File # K171984

8.1. Date prepared **September 19, 2017**

8.2. Submitter's information

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8.3. Trade Name, Common Name, Classification

Trade Name:	Clickfine Pen Needle and Penfine Classic Pen Needle
Common Name:	Injection Pen Needle
Classification Name:	Hypodermic single lumen needle
Regulation Number:	21 CFR 880.5570
Regulatory Class:	Class II
Product Code	FMI

8.4. Identification of predicate Device(s)

The identified predicate device within this submission are as follows:

Manufacturer:	Ypsomed AG
Trade Name:	Clickfine Pen Needle and Penfine Classic Pen Needle
Common Name:	Injection Pen Needle
Classification Name:	Hypodermic single lumen needle
Regulation Number:	21 CFR 880.5570
Regulatory Class:	Class II
Product Code	FMI
FDA 510(k) #:	K150662

8.5. Comparison with Predicate Devices:

The subject device has the same materials, fundamental scientific technology and device performance as the predicate device (K150662). The only difference is that the subject devices of the same gauge (outer diameter) will now have a larger inner diameter, i.e. extra thin walled needles according to ISO 9626:2016.

The table below provides a side by side comparison of the subject device compared to its predicate.

Characteristic	Predicate device	Subject device	Comments
Indications for use	The Clickfine and Penfine Classic Pen Needle are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.	The Clickfine and Penfine Classic Pen Needle are intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide.	Unchanged
Needle length	4, 4.5, 5, 6, 8, 10, and 12 mm	4, 4.5, 5, 6, 8, 10, and 12 mm	Unchanged
Needle gauge	32, 31, 30 and 29 gauge	32, 31, 30 and 29 gauge	Unchanged
Needle outer diameter	0.23 mm, 0.25, 0.3 and 0.33 mm	0.23 mm, 0.25, 0.3 and 0.33 mm	Unchanged
Needle inner diameter	Normal walled needle: ≥ 0.114 mm (31 gauge) ≥ 0.133 mm (30 gauge) ≥ 0.133 mm (29 gauge)	Normal walled needle: ≥ 0.114 mm (31 gauge) ≥ 0.133 mm (30 gauge) ≥ 0.133 mm (29 gauge)	Unchanged
	Thin walled needle: ≥ 0.105 mm (32 gauge) ≥ 0.125 mm (31 gauge) ≥ 0.165 mm (30 gauge) ≥ 0.190 mm (29 gauge)	Thin walled needle: ≥ 0.105 mm (32 gauge) ≥ 0.125 mm (31 gauge) ≥ 0.165 mm (30 gauge) ≥ 0.190 mm (29 gauge)	Unchanged
	n/a	Extra thin walled needle: ≥ 0.146 mm (31 gauge), ≥ 0.125 mm (32 gauge)	The needles have been modified to have Extra thin wall tubing

8.6. **Description of the Device**

The subject devices are sterile, non-pyrogenic, single use pen needles designed to be used with commercially available pen-injectors. The back end of the needle punctures the rubber injection port of the drug reservoir in the pen. When the injection is needed, the needle is inserted into the chosen site and the pen-injector delivers the fluid through the needle.

The materials of construction, (siliconized stainless-steel needle encased in a polypropylene hub with a polypropylene protective cap) as well as the sterile packaging (a polypropylene outer protective container and the peel tab) which provides the sterile barrier and the manufacturing (which includes radiation sterilization) are unchanged from the currently marketed devices. They subject devices will be marketed in the same

sizes as the predicate devices – 32 and 31 gauges and 4, 4.5, 5, 6, 8, 10, and 12 mm lengths.

8.7. Indication for Use

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

8.8. Technological Characteristics

The predicate device Clickfine and the Penfine Classic pen needle are comprised of a siliconized stainless steel needle encased in a needle hub. An outer protective cap snaps onto the hub over the needle. This assembly fits into a larger outer protective container, which provides the sterile barrier along with the peel foil.
These characteristics remain the same for the proposed devices.

8.9. Substantial Equivalence

Performance testing:
All Subject Device Pen Needles have met the requirements of the relevant sections of the following standards recognized by FDA:

a) ISO 11608-2:2012 Needle based injection systems for medical use - Requirements and test methods - Part 2: Needles
b) ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
c) ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods

The following risks were adequately addressed through design controls:

Device Modification	Risks	Verification Activity	Acceptance Criteria	Results of Verification
Larger inner diameter of needle on 31 Gauge and 32 Gauge needles	Breakage of needle	Testing for resistance to breakage was conducted acc. ISO 9626:2016	When tested acc. Annex C of ISO 9626:2016, the tubing shall not show visible breakage when examined by normal or corrected vision after testing.	All samples tested met the acceptance criteria for resistance to breakage acc. ISO 9626:2016.
	Bending of needle	Testing for stiffness was conducted acc. ISO 9626:2016	The tubing shall show a maximum defined deflection when tested in accordance with annex B of ISO 9626:2016: max. deflection 0.22 mm for 32 G and max. 0.21 mm for 31 G	All samples tested met the acceptance criteria for stiffness acc. ISO 9626:2016.
Change in labeling to add information regarding increased inner diameter	None	None Required. Changes do not impact the safe or effective use of the product	N/A	N/A

8.10. Conclusion

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 subject device is substantially equivalent to the predicate device.