510(k) Summary for K163400

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Date Prepared:	July 24, 2017
1.1. Trade/Proprietary Name:	Orbit Inserter
1.2. Common/Usual Name:	Spring loaded insertion device
1.3. Classification Name:	Introducer, syringe needle
1.4. Classification: Panel: Product Code: Regulation Number:	Class: II 80 KZH 21 CFR 880.6920
1.5. Purpose of Submission:	To introduce an optional inserter for Orbit Infusion Sets to the marketplace.
1.6. Predicate Devices:	Quick-serter (K992300) Product Code: KZH Regulation Number: 21 CFR 880.6920

1.7. Device Description

The Orbit Inserter is a manually operated, spring-loaded insertion aid for automatic insertion of compatible Orbit infusion sets. It assists the user with insertion of the infusion set cannula into the subcutaneous tissue.
The device is non-invasive, non-sterile and intended for multiple uses by the same patient. The Orbit Inserter is made of plastic and is powered by a stainless-steel spring.

1.8. Indication for Use:

The Orbit Inserter is indicated to aid the user with the insertion of the cannula into the subcutaneous tissue for compatible infusion sets listed on the labeling.

1.9. Intended Use:

The Orbit Inserter is intended to be used to assist patients and their caregivers by providing a mechanism to automate the insertion of compatible Ypsomed Infusion Sets primarily in a home setting.

1.10. Technological Characteristics:

The technological characteristics of the Orbit Inserter are the same as for the predicate devices (no significant change in the materials, design, energy source), they all are manually actuated and use a spring to provide the energy (force) to automatically insert the infusion set cannula into the infusion site.

Characteristic	**Orbit Inserter**	**Quick-serter**	**Comments**
Material of components			
Inserter	Plastic	Plastic	**Same**
Spring	Metal	Metal	**Same**
Design/Energy Source			
Energy Source	Spring-driven device	Spring-driven device	**Same**
Method of Activation	Manual Activation with One button	Manual Activation with Two buttons	**Different mechanism to activate the device**
Lifetime	2 years	3 years	**Different, validated Lifetime claim is company preference**

1.11. Performance Data:

Ypsomed has verified the Dimensional and functional specifications initially and after 550 activations. Biocompatibility was also tested and confirmed. A Summative user validation was performed confirming that the device could be used safely by the intended user groups after reading the instructions for use and without formal training.

The verifications have shown evidence that the Orbit Inserter meets the acceptance criteria of the performance requirements. Based on the results it can be concluded that the device performance is acceptable for the product.

Test	Specification	Results
Dimensional	Devices must meet Dimensional Specification	Pass
Visual inspection	No cracking No gross discoloration	Pass
Functional Testing	Meets Functional Specifications for: • Activation Torque • Button Activation force • Insertion Force • Reset Torque	Pass
Biological	ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
Usability	Successful Summative HF Validation	Pass
Life-cycle Testing	Meets Visual and Functional requirements after 550 activations	Pass

1.12. Conclusion

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