510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K210544

B Applicant

Unomedical a/s

C Proprietary and Established Names

Medtronic Extended infusion set

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
FPA	Class II	21 CFR 880.5440 - Intravascular administration set	General Hospital

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Type of Test:

Not applicable

III Intended Use/Indications for Use:

A Intended Use(s):

The infusion set is indicated for subcutaneous infusion of insulin in the treatment of diabetes mellitus. Refer to the Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.

B Indication(s) for Use:

The Medtronic Extended infusion set is indicated for subcutaneous infusion of medication administered by an external pump. The infusion set is indicated for single use.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The infusion set is indicated for subcutaneous use only. Do not use the infusion set for intravenous infusion. Do not use the infusion set with blood or blood products.

The infusion set may be worn for a maximum of seven days, or according to the insulin labeling, whichever duration is shorter.

If the infusion set is being used for the first time, do the first set-up in the presence of a healthcare professional.

IV Device Description:

The Medtronic Extended infusion set manufactured by Unomedical a/s is a sterile, non-pyrogenic, single use subcutaneous infusion set which includes a 90-degree soft cannula. It is delivered ready to use in a pre-loaded insertion device with automatic needle retraction. The infusion set is indicated for subcutaneous infusion of insulin administered by an external pump in the treatment of diabetes mellitus. Users should refer to Medtronic insulin pump user guide for a list of complete insulins and infusion sets.

The insertion needle and soft cannula of the Medtronic Extended infusion set are not accessible to the user before, during and after insertion of the soft cannula. This feature is intended prevent needle stick injuries as the device does not require loading with the needle by the user. The needle is then automatically retracted after use.

The device is comprised of two main components: the serter (which includes a release button, a cover, and a protective cap for the base) and the administration set (which includes a protective cap for connector, a connection with connection needle, extruded tube, fixation tape, and the tubing connector).

The Medtronic Extended infusion set is designed to be used with a Medtronic Insulin infusion pump for up to 7 days.

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

V Substantial Equivalence Information:

A Predicate Device Name(s):
MiniMed™ Mio™ Advance Infusion Sets

B Predicate 510(k) Number(s):
K173879

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210544	K173879
Device Trade Name	Medtronic Extended infusion set	MiniMed™ Mio™ Advance Infusion Sets
General Device Characteristic Similarities		
Intended Use/Indications For Use	The infusion set is indicated for the subcutaneous infusion of medication from an external pump.	Same
Mechanism of Action	The infusion set is an infusion administration set, connecting to a reservoir/infusion pump and inserted in the subcutaneous tissue of a user.	Same
Device components	Serter and administration set	Same
General Device Characteristic Differences		
Shelf Life	2 years	3 years

General Device Characteristic Differences		
Tubing **Inner Diameter** **Outer Diameter**	0.406 mm, 1.52 mm	0.385 mm, 1.50 mm
Tubing Length	46, 60, 80, 110 cm	46, 60. 110 cm
Time of Use	Up to 168 hours (7 days)	Up to 72 hours (3 days)

VI Standards/Guidance Documents Referenced:

ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residual

ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11737-1:2018, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products

ISO 11737-2:2019, Sterilization of medical devices – Microbiological methods – Part 2: Test of sterility performed in the definition, validation, and maintenance of a sterilization process

ASTM F1980-16: 2016, Standard Guide for Accelerated Aging Sterile Barrier Systems for Medical Devices

EN 556-1:2001 & EN556-1/AC:2006, "Sterilization of medical devices – Requirements for medical devices to be designated "Sterile"- Part 1: Requirements for terminally sterilized medical devices"

EN ISO 11138-1: 2017, "Sterilization of heath care products – Biological indicators – Part 1: General Requirements"

EN ISO 11138-2: 2017, "Sterilization of heath care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes"

ISO 11607-1:2019, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

ISO 11607-2:2019, Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes

ISO 15223-1:2016, Medical devices – Symbols to be used with medical devices labels, labeling, and information to be supplied – Part 1: General requirements

EN ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

ISO 10993-3:2014, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity

ISO 10993-4:2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood

ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for in-vitro Cytotoxicity

ISO 10993-6:2016, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation

EN ISO 10993-7:2008 & EN ISO 10993-7/AC:2009, Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals

ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

EN ISO 10993-11:2017, Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity

ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials

ISO 10993-17:2002, Biological Evaluation of Medical Devices – Part 17: Establishment of Allowable Limits for Leachable Substances

EN ISO 10993-18:2009, Biological Evaluation of Medical Devices – Part 18: Chemical characterization of materials

EN ISO 8536-8:2015 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed

ISO 8536-9:2015 Infusion Equipment for Medical Use – Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment

ASTM D4169-16 – Standard Practice for Performance Testing of Shipping Containers and Systems

IEC 62366-1:2015/AC, “Medical devices – Part 1: Application of usability engineering to medical devices”

ISO 14971:2019, Medical devices – Application of risk management to medical devices.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The following analytical performance tests were conducted:

1. Functional tests
    - Leak/Tightness
    - Flow (Occlusion)
    - Tensile tests of introducer needle from needle hub, tubing connections, soft cannula from Fluid Part assembly, adhesive tape from base, connector from base, connector needle from connector
    - Strength tests of Fluid Part assembly from base assembly, base assembly from cylinder, serter activation force (intended and unintended), disassembly of cylinder from cover
    - Serter functionality tests
2. Packaging tests:
    - Dynamic and Visual Peel Test
    - Print on Packaging and labelling
3. Transportation Tests:
    - Transportation tests general
4. Compatibility Tests:
    - Drug and Device Compatibility
5. Dimensional Tests:
    - Distance soft cannula to set
    - Distance of introducer needle bevel to soft cannula
    - Length of tubes
6. Biocompatibility Testing in accordance with ISO 10993-1
7. EO/ECH residuals Testing
8. Pyrogen/Endotoxin Testing
9. Shelf life Testing
10. Sterilization Testing
11. Usability Testing

B Other Supportive Instrument Performance Characteristics Data:

Summary of Clinical Testing:
A multi-center, non-randomized, prospective single arm study on the Medtronic Extended infusion set was conducted in patients with Type 1 Diabetes on insulin pump therapy with Continuous Glucose Monitoring (CGM). A total of up to 300 subjects were enrolled at up to 20 investigational sites within the United States in order to have 240 subjects meet eligibility criteria. Each subject wore their own MiniMed™ 670G insulin system and was given 12 infusion sets to wear. Each infusion set was worn for at least 174 hours, or until infusion set failure if this occurred before 174 hours. The infusion set with the longest length (43 inches) was used for this study and subjects were asked to change insulin reservoirs at least every 174 hours. The infusion set(s) or reservoir(s) could be replaced independent of each other as referenced in subject instructions. The time of infusion set insertion was taken from user's daily logs.

The survival rate at the end of day 7 was 73.4% for Humalog, 76.4% for Novolog, and 74.8% overall. The following tables summarize the descriptive summary of all infusion set removals in the Intend-to-Treat (ITT) group as reported by subjects. All causes of infusion set removals were collected and analyzed. One infusion set could have recorded more than one removal reason. 574 removals not categorized as scheduled removals were associated with a reason for removal identified in the protocol, such as removal due to discomfort of site, accidental removals, kinked or bent cannula, leakage, loss of insertion (e.g., patient did not appear to be receiving insulin within 12 hours after infusion set was inserted), mechanical failure, and adhesive issues. However, there were 360 removals categorized as "other" when reason for infusion set removal did not fit into any of the predefined reasons as described below. Those removals included: miscalculating the removal time (234 times); subject personal decision of removal when BG was higher than their comfort level (73 times); and other reasons (53) unrelated to the Medtronic Extended infusion set use.

Summary of the Primary Removal Reasons, ITT Population, Humalog									
Patient selections	**Overall % (n)**	**Day 01 (0 – 24 hrs)**	**Day 02 (24 – 48 hrs)**	**Day 03 (48 – 72 hrs)**	**Day 04 (72 – 96 hrs)**	**Day 05 (96 – 120 hrs)**	**Day 06 (120 – 144 hrs)**	**Day 07 (144 – 168 hrs)**	**Beyond Day 07**
Scheduled removal	67.5% (1054)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	67.5% (1054)
Unexplained Hyperglycemia	0.8% (13)	0% (0)	0.1% (1)	0% (0)	0.1% (2)	0.2% (3)	0.3% (5)	0.1% (2)	0% (0)
Leakage	1.7% (27)	0% (0)	0.2% (3)	0.1% (2)	0.5% (7)	0.5% (7)	0.2% (3)	0.3% (4)	0.1% (1)
Accidental removals	7.5% (117)	0.5% (7)	0.9% (14)	0.6% (10)	0.9% (14)	1.2% (18)	1.3% (20)	1.6% (25)	0.6% (9)
Loss of insertion	0.1% (1)	0% (0)	0.1% (1)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Adhesive issue	5.6% (88)	0.4% (6)	0.5% (8)	0.3% (5)	0.6% (9)	0.9% (14)	1.2% (19)	1.4% (21)	0.4% (6)
Removal due to discomfort at site	1.5% (23)	0.1% (2)	0% (0)	0.1% (1)	0.3% (4)	0.5% (7)	0.4% (6)	0.1% (2)	0.1% (1)
Presence of serum ketones	0.4% (7)	0% (0)	0% (0)	0% (0)	0.1% (1)	0.1% (1)	0.1% (1)	0.2% (3)	0.1% (1)
Signs of infection at the infusion site	0.4% (6)	0% (0)	0% (0)	0.1% (1)	0% (0)	0% (0)	0% (0)	0.3% (5)	0% (0)
Mechanical failure	1.0% (15)	0.1% (2)	0.1% (1)	0.2% (3)	0.1% (1)	0.1% (1)	0.1% (1)	0.4% (6)	0% (0)
Kinked or bent cannula	0.3% (4)	0.1% (1)	0% (0)	0% (0)	0% (0)	0.1% (1)	0% (0)	0.1% (2)	0% (0)
Removal other	13.2% (206)	0.5% (8)	0.1% (1)	0.1% (1)	0.5% (8)	0.9% (14)	1.0% (15)	5.5% (86)	4.7% (73)
Total	100% (1561)	1.7% (26)	1.9% (29)	1.5% (23)	2.9% (46)	4.2% (66)	4.5% (70)	10.0% (156)	73.4 % (1145)

Summary of the Primary Removal Reasons, ITT Population, Novolog									
Patient selections	**Overall % (n)**	**Day 01 (0 – 24 hrs)**	**Day 02 (24 – 48 hrs)**	**Day 03 (48 – 72 hrs)**	**Day 04 (72 – 96 hrs)**	**Day 05 (96 – 120 hrs)**	**Day 06 (120 – 144 hrs)**	**Day 07 (144 – 168 hrs)**	**Beyond Day 07**
Scheduled removal	71.9% (1064)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	71.9% (1064)
Unexplained Hyperglycemia	0.6% (9)	0% (0)	0% (0)	0% (0)	0.1% (2)	0.1% (2)	0.1% (2)	0.2% (3)	0% (0)
Leakage	2.2% (33)	0.1% (1)	0% (0)	0.4% (6)	0.4% (6)	0.3% (4)	0.5% (8)	0.5% (8)	0% (0)
Accidental removals	5.9% (87)	0.4% (6)	0.6% (9)	0.6% (9)	1.1% (16)	0.9% (13)	0.7% (10)	1.2% (18)	0.4% (6)
Loss of insertion	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)	0% (0)
Adhesive issue	6.4% (94)	0.5% (7)	0.4% (6)	0.5% (8)	0.7% (10)	0.9% (13)	1.2% (18)	1.5% (22)	0.7% (10)
Removal due to discomfort at site	0.9% (14)	0.1% (1)	0% (0)	0.2% (3)	0.1% (1)	0.1% (2)	0% (0)	0.3% (5)	0.1% (2)
Presence of serum ketones	0.5% (7)	0.1% (1)	0% (0)	0.1% (1)	0.1% (2)	0% (0)	0.1% (1)	0.1% (2)	0% (0)
Signs of infection at the infusion site	0.4% (6)	0% (0)	0% (0)	0% (0)	0% (0)	0.1% (1)	0.1% (1)	0.3% (4)	0% (0)
Mechanical failure	0.9% (13)	0% (0)	0.1% (2)	0.1% (1)	0.1% (1)	0.1% (2)	0.1% (2)	0.3% (5)	0% (0)
Kinked or bent cannula	0.2% (3)	0% (0)	0% (0)	0% (0)	0.1% (2)	0% (0)	0% (0)	0% (0)	0.1% (1)
Removal other	10.1% (150)	0.3% (4)	0.1% (1)	0.5% (7)	0.4% (6)	0.6% (9)	0.5% (8)	4.5% (67)	3.2% (48)
Total	100% (1480)	1.4% (20)	1.2% (18)	2.4% (35)	3.1% (46)	3.1% (46)	3.4% (50)	9.1% (134)	76.4% (1131)

Removal Reason Term, Expanded Definition	
Term	**Expanded Definition**
Scheduled removal	Scheduled removal refers to subject wearing the infusion set for 174 hours or more
Accidental removal	Accidental removal refers to infusion set getting caught on something, or someone or something physically pulling on the infusion set, causing it to be accidentally removed
Loss of insertion	Loss of insertion (e.g., patient does not appear to be receiving insulin within 12 hours after infusion set is inserted)

Removal Reason Term, Expanded Definition	
Term	**Expanded Definition**
Unexplained Hyperglycemia	Study meter glucose >250 mg/dL >3 hours postmeal which may include time during the subject's sleeping hours and failure of a correction dose(s) to lower the study meter glucose by at least 50 mg/dL.
Presence of serum ketones	The term "presence of serum ketones" refers to severe hyperglycemia. This term is derived from the field in the CRF which stated the following: the presence of serum ketones >= 0.66 mmol/L with a study meter glucose >250 mg/dL in the absence of illness and blood glucose that does not respond to insulin correction dose(s). This is the definitions of severe hyperglycemia.
Signs of infection at the infusion site	There are signs of infection at the infusion site (i.e., erythema (>1 cm in diameters) with warmth, pain, and/or induration)

The following tables show a summary of adverse events observed during the clinical study and were used to evaluate the safety of the device.

Summary of Adverse Events, Rate of 100 Patient Years, Data from subjects using Humalog			
Category	**Number of Subjects with Events (N)**	**Number of Events (N)**	**Number of Events per 100 Patient Year**
Serious Adverse Events (SAE)	2	2	5
Serious Adverse Device Effects (SADE)	0	0	0
Unanticipated Adverse Device Effects (UADE)	0	0	0
Severe Hypoglycemia	2	2	5
Severe Hyperglycemia	22	46	114.4
DKA	0	0	0
Skin infections at infusion set insertion site	5	6	14.9

Summary of Adverse Events, Rate of 100 Patient Years, Data from subjects using Novolog			
Category	**Number of Subjects with Events (N)**	**Number of Events (N)**	**Number of Events per 100 Patient Year**
Serious Adverse Events (SAE)	1	1	2.5
Serious Adverse Device Effects (SADE)	0	0	0
Unanticipated Adverse Device Effects (UADE)	0	0	0
Severe Hypoglycemia	0	0	0
Severe Hyperglycemia	24	37	93.5
DKA	0	0	0
Skin infections at infusion set insertion site	10	10	25.3

The rate of infusion set failure due to unexplained hyperglycemia (i.e. suspected occlusion) at the end of day 7 is presented below for subjects using Humalog or Novolog in the ITT population. The rate of infusion set failure is defined as the number of infusion set removals associated with unexplained hyperglycemia divided by total number of infusion sets inserted. In addition, site effect was evaluated. However, due to the low number of events among the sites, significance level cannot be evaluated.

Rate of Infusion Set Failure Due to Unexplained Hyperglycemia at the end of the Day 7, Humalog, ITT Population						
Number of Subjects	**Number of Infusion Sets**	**Number of failed infusion sets due to unexplained Hyperglycemia (number of subjects)**	**Rate of infusion set failure**	**Prespecified threshold (upper CL)**	**Actual result (upper CL)**	**Success criteria met?**
132	1561	2 (2)	0.13%	20%	0.51%	Yes

Rate of Infusion Set Failure Due to Unexplained Hyperglycemia at the end of the Day 7, Novolog, ITT Population						
Number of Subjects	**Number of Infusion Sets**	**Number of failed infusion sets due to unexplained Hyperglycemia (number of subjects)**	**Rate of infusion set failure**	**Prespecified threshold (upper CL)**	**Actual result (upper CL)**	**Success criteria met?**
127	1480	6 (5)	0.41%	20%	1.00%	Yes

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.