DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 1, 2017

Unomedical A/S
% Lee Leichter
President
P/l Biomedical
10882 Stonington Avenue
Fort Myers, Florida 33913

Re: K162812
Trade/Device Name: Unomedical Comfort Subcutaneous Infusion Set, Unomedical Comfort Short Subcutaneous Infusion Set, Unomedical Neria Soft Subcutaneous Infusion Set, Medtronic Silhouette Subcutaneous Infusion Set, Medtronic Silhouette Paradigm Subcutaneous Infusion Set, Roche Accu-chek Tender Subcutaneous Infusion Set, Asante Comfort Subcutaneous Infusion Set, Abbott Comfort Subcutaneous Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: August 31, 2017
Received: September 1, 2017

Dear Lee 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 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" (21 CFR 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162812

Device Name
Unomedical Comfort™ Subcutaneous Infusion Set
Unomedical Comfort Short™ Subcutaneous Infusion Set
Unomedical Neria Soft Subcutaneous Infusion Set

Indications for Use *(Describe)*
The Unomedical Comfort™ Subcutaneous Infusion Set and Unomedical Comfort Short™ Subcutaneous Infusion Set are indicated for subcutaneous infusion of insulin administered by an external pump.

The Unomedical Neria Soft Subcutaneous Infusion Set is indicated for subcutaneous infusion of medication administered by an external pump.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162812

Device Name
Medtronic Silhouette® Subcutaneous (Luer Lock) Infusion Set
Medtronic Silhouette Paradigm® Subcutaneous Infusion Set

Indications for Use *(Describe)*
The Medtronic Silhouette® Subcutaneous (Luer Lock) Infusion Set is indicated for subcutaneous infusion of insulin from and infusion pump.

The Medtronic Silhouette Paradigm® Subcutaneous Infusion Set is indicated for use with Medtronic Paradigm Insulin Subcutaneous Infusion Pumps for continuous subcutaneous insulin infusion by patients or caregivers in the home environment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K162812

Device Name
Roche Accu-Chek Tender™ Subcutaneous Infusion Set
Asante Comfort™ Subcutaneous Infusion Set
Abbott Comfort™ Subcutaneous Infusion Set

Indications for Use *(Describe)*
The Roche Accu-Chek Tender™ Subcutaneous Infusion Set is indicated for subcutaneous infusion of insulin administered with microdosage insulin pumps.

The Asante Comfort™ Subcutaneous Infusion Set is indicated for subcutaneous infusion of insulin administered by the Snap™ Insulin Pump System.

The Abbott Comfort™ Subcutaneous Infusion Set is indicated for infusion of fluids into the body below the surface of the skin when attached to a fluid reservoir of a compatible Abbott pump.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

"510(K) SUMMARY"

Submitted By/Contact Person:
John M. Lindskog
President
Unomedical A/S Infusion Devices
Aaholmvej 1-3, Osted
DK-4320 Lejre, Denmark
Telephone: + 45 46 42 78 10 (CET 0800-1700)
Fax: + 45 46 42 78 65
E-mail: John.Lindskog@convatec.com

Date Prepared: 27 August 2017

7.1 510(k) Number: K162812

7.2 Trade/Proprietary Name:
Unomedical Comfort™ Subcutaneous Infusion set
Unomedical Comfort Short™ Subcutaneous Infusion Set
Unomedical Neria Soft Subcutaneous Infusion Set
Medtronic Silhouette® Subcutaneous (Luer Lock) Infusion Set
Medtronic Silhouette Paradigm® Subcutaneous Infusion Set
Roche Accu-Chek Tender™ Subcutaneous Infusion Set
Asante Comfort™ Subcutaneous Infusion Set
Abbott Comfort™ Subcutaneous Infusion Set

7.3 Common/Usual Name Subcutaneous Infusion Set

7.4 Classification Name Intravascular Administration Set

7.5 Classification Class: II
Panel: 80
Product Code: FPA
Regulation: 21 CFR 880.5440

7.6 Purpose of Submission
To accurately describe the currently marketed iterates of the Comfort Subcutaneous Infusion set line manufactured in multiple configurations, in multiple facilities and marketed under several brand names by several different companies.

The only changes to the devices included in this submission that were not previously cleared were the change in sterilization facility and the change to a PFOA free silicone cannula, which was done under the U.S. Environmental Protection Agency PFOA Stewardship Program. These changes are supported by this submission.

7.7 Substantial Equivalence

The Comfort™ subcutaneous infusion Sets are substantially equivalent to the Subcutaneous Infusion Sets cleared under the following 510(k)s:
K972135 – Maersk Medical Pureline Comfort Subcutaneous Infusion Set
K051264 – Abbott Comfort™ Subcutaneous Infusion Set
K120872 – Asante Comfort™ Subcutaneous Infusion Set
K160648 – Medtronic Silhouette® Paradigm Infusion Set

7.8 Predicate Devices

The devices that serve as predicates for each of the subject devices is identified in Table 1.

7.9 Device Description

The Comfort Subcutaneous Infusion Sets are sterile, non-pyrogenic, single use subcutaneous infusion sets. The current sets are designed to be used with commercially available infusion devices or are indicated for a specific pump where the set has a proprietary pump reservoir connection (e.g. Medtronic, Asante). Each has two basic components provided for each device. The first is a stand-alone subcutaneous indwelling Soft Cannula. This component of the set is provided as an integral assembly with a PFOA-Free PTFE soft cannula, adhesive backed fixation tape, an injection port and the female portion of a proprietary plastic "click-lock" connector. The assembly comes with a stainless-steel insertion needle. The insertion needle is mounted to a male portion of the proprietary plastic “click-lock" connector. The insertion needle comes to the user inserted through the injection port and the inner lumen of the soft cannula with the needle end protruding past the tip of the soft cannula. The male connector is locked to the female connector on the indwelling soft cannula. A needle protector is assembled over the soft cannula and the insertion needle. A separate male portion of the proprietary connector without the insertion needle is provided in the package. This component is used to attach to the female connector after the indwelling soft cannula has been inserted and the steel insertion needle has been withdrawn and protects the indwelling cannula when the infusion set is not attached. Each Soft cannula set comes individually packaged in its own blister pack sealed with paper lid stock.

The second component is the infusion tubing set. The infusion tubing set for all sets are comprised of a co-extruded tube with a stainless-steel needle incorporated into the male portion of the proprietary plastic "click-lock" connector at the patient end. The proximal end of the current Comfort set terminates in either a standard luer lock connector or a proprietary connector compatible with the specified pump. The sets come individually packaged in blister packs sealed with paper lid stock.

7.10 Indication for Use

The Indications for use for each set is provided in Table 1.

7.11 Intended Use

The intended use of these sets has not changed. These sets remain intended to be used for subcutaneous infusion of insulin or medication when connected to a compatible pump. The specific drug (insulin or medication) and the specific compatible pump differ depending on the intended use of each infusion set.

7.12 Technological Characteristics

The technological characteristics of all the Comfort Subcutaneous infusion Sets (regardless of the branding) have not changed. The device's operating principle(s) or mechanism of action, configurations (models, lengths, etc.), performance specifications, and packaging have not changed. All changes in the materials of construction or design of any of the devices have already been submitted on at least one of the family of devices. All of these changes have been previously cleared except the change from of the PFTE Soft Cannula to a PFOA-Free PTFE Soft Cannula (due to mandatory material discontinuation by the supplier in compliance with the U.S. Environmental Protection Agency PFOA Stewardship Program); which is cleared in this submission. This new material was extracted and analyzed per ISO 10993 and found to substantially equivalent to the PTFE material. This submission is to ensure that the information at the FDA on these devices is consistent with the latest configurations. Table 1 provides a comparison of the key characteristics of the devices.

7.13 Performance Data

The following verification testing was performed:

7.8.1 Flow test:

7.8.1.1 Tubing Set – 40 ml/min at 1 bar pressure

7.8.2 Leak test:

7.8.2.1 Luer-Lock - No Leaks at 3 bar pressure for 30 seconds

7.8.2.2 Pcap - No Leaks at 1.4 bar pressure for 30 seconds

7.8.2.3 Asante Hub - No Leaks at 0.56 bar pressure for 30 seconds

7.8.3 Pull tests:

7.8.3.1 Soft Cannula to Cannula housing: 3 N, Dynamic Pull

7.8.3.2 Tubing to tubing Luer-lock: 15 N, Dynamic pull

7.8.3.3 Tubing to Needle Connector: 15 N, Dynamic pull

7.8.3.4 Cannula housing to Needle Connector: 15 N, Dynamic pull

7.8.3.5 Cannula housing to Adhesive: 15 N, Dynamic pull

7.8.4 Bend test:

7.8.4.1 No leaks and no break at the tubing after 3000 bendings

7.14 Conclusion

Unomedical A/S confirmed that the devices passed all testing and concluded that the Subject Devices are substantially equivalent to the predicate devices currently legally marketed in the USA.

TABLE 1

SUBJECT DEVICE BRAND NAMES	UNOMEDICAL COMFORT	UNOMEDICAL COMFORT - SHORT	MEDTRONIC SILHOUETTE® LUER LOCK INFUSION SET	ROCHE ACCUCHECK TENDER	UNOMEDICAL NERIA SOFT	MEDTRONIC SILHOUETTE® PARADIGM®	ABBOTT COMFORT	ASANTE COMFORT
PREDICATE 510(K) FILE NUMBER	K972135	K972135	K972135	K972135	K972135	K160648	K051264*	K120872
PREDICATE NAME	MAERSK MEDICAL PURELINE COMFORT SUBCUTANEOUS INFUSION SET	MAERSK MEDICAL PURELINE COMFORT SUBCUTANEOUS INFUSION SET	MAERSK MEDICAL PURELINE COMFORT SUBCUTANEOUS INFUSION SET	MAERSK MEDICAL PURELINE COMFORT SUBCUTANEOUS INFUSION SET	MAERSK MEDICAL PURELINE COMFORT SUBCUTANEOUS INFUSION SET	MEDTRONIC SILHOUETTE® PARADIGM®	ABBOTT COMFORT SUBCUTANEOUS INFUSION SET	ASANTE COMFORT SUBCUTANEOUS INFUSION SET
CLEARED INDICATIONS FOR USE	INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN.	INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN.	INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN.	INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN.	INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN.	FOR USE WITH MEDTRONIC PARADIGM INSULIN SUBCUTANEOUS INFUSION PUMPS FOR CONTINUOUS SUBCUTANEOUS INSULIN INFUSION BY PATIENTS OR CAREGIVERS IN THE HOME ENVIRONMENT.	INFUSION OF FLUIDS INTO THE BODY BELOW THE SURFACE OF THE SKIN WHEN ATTACHED TO A FLUID RESERVOIR OF A COMPATIBLE ABBOTT PUMP	SUBCUTANEOUS INFUSION OF MEDICATION, INCLUDING INSULIN, ADMINISTERED BY THE PEARL™ EXTERNAL INSULIN PUMP SYSTEM
PROPOSED INDICATIONS FOR USE (K162812)	SUBCUTANEOUS INFUSION OF INSULIN ADMINISTERED BY AN EXTERNAL PUMP	SUBCUTANEOUS INFUSION OF INSULIN ADMINISTERED BY AN EXTERNAL PUMP	SUBCUTANEOUS INFUSION OF INSULIN FROM AN INFUSION PUMP	SUBCUTANEOUS INFUSION OF INSULIN ADMINISTERED WITH MICRODOSAGE INSULIN PUMPS.	SUBCUTANEOUS INFUSION OF MEDICATION ADMINISTERED BY AN EXTERNAL PUMP	NO CHANGE	NO CHANGE (IF COMMERCIALIZED)	SUBCUTANEOUS INFUSION OF INSULIN ADMINISTERED BY THE SNAP™ INSULIN PUMP SYSTEM
DETAIL OF DIFFERENCES	SUBCUTANEOUS INFUSION ~~AND/OR INJECTION~~ OF ~~FLUIDS~~ INSULIN ~~INTO THE BODY~~	SUBCUTANEOUS INFUSION ~~AND/OR INJECTION~~ OF ~~FLUIDS~~ INSULIN ~~INTO THE BODY~~	SUBCUTANEOUS INFUSION ~~AND/OR INJECTION~~ OF ~~FLUIDS~~ INSULIN ~~INTO THE BODY~~	SUBCUTANEOUS INFUSION ~~AND/OR INJECTION~~ OF ~~FLUIDS~~ INSULIN ~~INTO~~	SUBCUTANEOUS INFUSION ~~AND/OR INJECTION~~ OF ~~FLUIDS~~ MEDICATION	NO CHANGE	NO CHANGE (IF COMMERCIALIZED)	SUBCUTANEOUS INFUSION OF ~~MEDICATION, INCLUDING~~ INSULIN, ADMINISTERED

	~~BELOW THE SURFACE OF THE SKIN~~ ADMINISTERED BY AN EXTERNAL PUMP.	~~BELOW THE SURFACE OF THE SKIN~~ ADMINISTERED BY AN EXTERNAL PUMP.	~~BELOW THE SURFACE OF THE SKIN~~ FROM AN INFUSION PUMP.	~~THE BODY BELOW THE SURFACE OF THE SKIN~~ ADMINISTERED WITH MICRODOSAGE INSULIN PUMPS.	~~INTO THE BODY BELOW THE SURFACE OF THE SKIN~~ ADMINISTERED BY AN EXTERNAL PUMP.			BY THE ~~PEARL™~~SNAP™ ~~EXTERNAL~~ INSULIN PUMP SYSTEM
INSTRUCTION FOR USE CHANGES	**NO SUBSTANTIVE CHANGE – INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN UPDATED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**	**NO SUBSTANTIVE CHANGE – INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN UPDATED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**	**NO SUBSTANTIVE CHANGE – INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN UPDATED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**	**NO SUBSTANTIVE CHANGE – INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN UPDATED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**	**NO SUBSTANTIVE CHANGE – INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN UPDATED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**	**NO CHANGE**	**IF COMMERCIALIZED, DRAFT INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION WILL BE FINALIZED AND STANDARDIZED**	**NO SUBSTANTIVE CHANGE – DRAFT INSTRUCTIONS FOR USE PROVIDED IN ORIGINAL SUBMISSION HAVE BEEN FINALIZED AND STANDARDIZED (ALL ARE PROVIDED IN APPENDIX II).**
STERILIZATION/ STERILIZATION LOCATION/ SUBCONTRACTORS CHANGES	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**	**IF COMMERCIALIZED, STERILIZATION SITE WILL BE CHANGED WITHOUT CHANGE TO STERILIZATION METHOD OR SAL.**	**CHANGE OF STERILIZATION SITE ONLY. *NO CHANGE* TO STERILIZATION METHOD OR SAL.**
MATERIALS/ COMPONENTS CHANGES	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**IF COMMERCIALIZED, THE SOFT CANNULA MATERIAL WILL BE MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**	**THE SOFT CANNULA MATERIAL WAS MODIFIED TO A PFOA FREE PTFE, (U.S. ENVIRONMENTAL PROTECTION AGENCY PFOA STEWARDSHIP PROGRAM).**

	THE SEPTUM WAS CHANGED FROM THERMOPLASTIC ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	THE SEPTUM WAS CHANGED FROM THERMOPLASTIC ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	THE SEPTUM WAS CHANGED FROM THERMOPLASTI C ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	THE SEPTUM WAS CHANGED FROM THERMOPLAST IC ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	THE SEPTUM WAS CHANGED FROM THERMOPLASTI C ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	THE SEPTUM WAS CHANGED FROM THERMOPLASTIC ELASTOMER (TPE) TO SILICONE RUBBER. THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K051264	NO CHANGE	NO CHANGE
	THE LUER LOCK CONNECTOR CHANGED FROM PVC (POLYVINYL CHLORIDE) TO MABS (METHYLMETHA CRYLATE ACRYLONITRILE BUTADIENE STYRENE). THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K032854	THE LUER LOCK CONNECTOR CHANGED FROM PVC (POLYVINYL CHLORIDE) TO MABS (METHYLMETHAC RYLATE ACRYLONITRILE BUTADIENE STYRENE). THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K032854	THE LUER LOCK CONNECTOR CHANGED FROM PVC (POLYVINYL CHLORIDE) TO MABS (METHYLMETHA CRYLATE ACRYLONITRILE BUTADIENE STYRENE). THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K032854	THE LUER LOCK CONNECTOR CHANGED FROM PVC (POLYVINYL CHLORIDE) TO MABS (METHYLMETH ACRYLATE ACRYLONITRIL E BUTADIENE STYRENE). THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K032854	THE LUER LOCK CONNECTOR CHANGED FROM PVC (POLYVINYL CHLORIDE) TO MABS (METHYLMETHA CRYLATE ACRYLONITRILE BUTADIENE STYRENE). THIS MATERIAL WAS IDENTIFIED AND CLEARED IN SUBMISSION K032854	NO CHANGE	NO CHANGE	NO CHANGE
SPECIFCATION/ TEST METHODS <u>CHANGES</u>	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	IF COMMERCIALIZED, A BENDING TEST WILL BE INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.	A BENDING TEST HAS BEEN INTRODUCED TO VERIFY ROBUSTESS OF TUBING BONDS WHEN SUBJECTED TO STRESSES SEEN DURING USE.

	A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**IF COMMERCIALIZED, A TENSION TEST WILL BE INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**	**A TENSION TEST HAS BEEN INTRODCUED AFTER PRE-CONDITIONING OF TEST SAMPLES IMMERSED IN 37^{O}C WATER FOR 18-24 HRS.**

*The Abbott Set was cleared but has not been commercialized