FEB 1 6 2012 K120337

Unomedical
A ConvaTec Company

Section 5 510(K) Summary

5.1 Administrative Information

Date of Submission ..... September 16, 2011

Submitter ..... Unomedical A/S, Infusion Devices
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5.2 Device Identification

Proprietary Name ..... i-port Advance™ injection port
Common Name ..... Injection Port
Classification Name ..... Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Classification ..... Class II per 21 CFR 880.5200, 80:FOZ

5.3 Indications for Use

The i-port Advance™ injection port is indicated for patients who administer, or to whom is administered, multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device may remain in place for up to 72 hours to accommodate multiple drug injections without the discomfort of additional needle sticks. The i-port Advance™ may be used on a wide range of patients, including adults and children. Model numbers for the device include 020110, 020210, 020102 and 020202.

These are the same indications previously cleared for the predicate i-port® injection port (K052389)

5.4 Predicate Devices

The i-port Advance™ is substantially equivalent to:
Patton Medical Devices i-port® injection port (K052389)
Unomedical A/S Inset™ Infusion Set (K032854)

5.5 Device Description

The i-port Advance™ injection port was designed and developed through a technological collaboration between Unomedical A/S and Patton Medical Devices and modifies the Patton Medical Device i-port® injection port (K052389) to include the automated insertion component ("Inserter") of the Unomedical Inset™ Infusion Set (K032854).

The Injection Port component is a prescription only, sterile, single use, non-pyrogenic, external, disposable injection port with an indwelling catheter through which physician-prescribed medications can be injected subcutaneously from a standard syringe and needle, pen or alternative manual injection device. The indwelling catheter is installed using the integrated Inserter, a manually-operated spring-loaded catheter insertion tool that introduces the indwelling catheter into the subcutaneous tissue by automatically inserting the prefixed introducer needle to a predetermined depth below the skin surface.

Once applied, the insertion needle is removed, and only the soft cannula remains under the skin, acting as a gateway to the subcutaneous tissue. The user injects medicines directly through the resealable septum at the top of the device. The needle of the syringe or insulin pen remains above the surface of the skin, while the medication is delivered through the soft cannula and into the subcutaneous tissue. The device, which may be worn for up to 72 hours and receive up to 75 injections, is designed to reduce the hardships of multiple daily subcutaneous injections.

The device will be marketed under four (4) model numbers:

Model No.	Catheter Length	Quantity.
020110	6 mm	10x
020210	9 mm	10x
020102	6 mm	2x
020202	9 mm	2x

5.6 Comparison of Technological Characteristics

The new device modifies the Patton Medical Device i-port® injection port (K052389) to include the same integrated Inserter found in the Unomedical Inset™ Infusion Set (K032854). Both functional components of the device remain largely unchanged and have the same technological characteristics as their respective predicate devices. The Injection Port component of the i-port Advance™ has the same design, materials composition, operating principles and performance characteristics as the i-port® injection port (K052389), and the automated Inserter component of the new device has the same design, materials composition, operating principles and performance characteristics as the automated Inserter component in the Inset™ Infusion Set (K032854). Although some minor dimensional changes have been made to some of the individual components to accommodate the integration of the Inserter with the Injection Port components, none of these modifications alter the intended use or impact the safety and effectiveness of the device.

5.7 Non-Clinical Performance and Safety Data

Performance testing was conducted in accordance with consensus standards and design control requirements. Results from testing confirm that the i-port Advance™ meets all applicable design and performance requirements. No new issues of safety and effectiveness were raised with the testing performed. Testing performed includes:

- Flow Testing (before and after maximum punctures) per internal Unomedical protocols
- Leak Testing (before and after maximum punctures) per internal Unomedical protocols
- Catheter Tension Testing per ISO 10555
- Introducer Needle Pull Testing per ISO 10555 and ISO 11070
- Adhesive Weld Strength Test per internal Unomedical protocols
- Injection Port Disconnection Strength Testing per internal Unomedical protocols
- Spring Loading Force Testing per internal Unomedical protocols
- Insertion Depth Testing per internal Unomedical protocols

A Risk Management Plan and a Risk Management File were established for the i-port Advance™ project. The Risk Management Plan is modeled after ISO 14971:2007, Medical devices - Application of risk management to medical devices. Risks were identified and through the use of Failure Modes, Effects, and Criticality Analysis (FMECA) and Fault Tree Analysis (FTA) risks were evaluated, and where possible, were mitigated. It was determined that the overall risks of the device are within the As Low as Reasonably Practicable (ALARP) and Broadly Acceptable regions for this type of device.

The materials used to fabricate the i-port Advance™ are biocompatible and safe for their intended use. The patient and drug contact materials on the i-port Advance™ are the same as those on the currently marketed predicate devices and meet the requirements of AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process for permanent body contact, external communicating device with indirect blood contact. The drug contact materials are the same as those used in the currently marketed predicate devices. The device contains no PVC and as such no DEHP plasticizers.

The i-port Advance™ is sterilized with Ethylene Oxide (EtO), and sterility is assured by using a validated sterilization method qualified in accordance with AAMI/ANSI/ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices to a sterility assurance level (SAL) of 10^{-6}. Ethylene oxide residual levels resulting from EtO sterilization will comply with AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals. The fluid path will be Pyrogen free as tested by limulus amebocyte lysate (LAL), and the packaging will be tested to applicable standards to ensure integrity and durability.

5.8 Statement of Substantial Equivalence

By definition, a new device is substantially equivalent to a predicate device when the new device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any new questions regarding its safety and effectiveness when compared to the predicate device.

The i-port Advance™ has the same intended use as the Patton Medical Devices i-port® injection port, (K052389). The i-port Advance™ has the same technological characteristics as the predicate devices in terms of functional design, components and materials, principals of operation, sterilization method and performance characteristics. On this basis, Unomedical A/S concludes that the i-port Advance™ injection port is substantially equivalent to the Patton Medical Devices i-port® injection port, (K052389) and the Unomedical A/S Inset™ Infusion Set (K032854) and does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Unomedical A/S
C/O Mr. William Sammons
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

FEB 1 6 2012

Re: K120337
Trade/Device Name: i-port Advance™ injection port
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: February 2, 2012
Received: February 3, 2012

Dear Mr. Sammons:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: n/a

Device Name: i-port Advance™ injection port

Indications for Use: The i-port Advance™ injection port is indicated for patients who administer, or to whom is administered, multiple daily subcutaneous injections of physician prescribed medications, including insulin. The device may remain in place for up to 72 hours to accommodate multiple drug injections without the discomfort of additional needle sticks. The i-port Advance™ may be used on a wide range of patients, including adults and children. Model numbers for the device include 020110, 020210, 020102 and 020202.

Prescription Use X AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2/15/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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