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PATTON medical devices

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Section 3.0 510(K) SUMMARY

3.1 Company and Contact Information

Submitters Name:	Regulatory Resources, LLC for Patton Medical Devices, LP
Address:	P.O. Box 1490 Eagle, ID 83616
Contact person:	Fred Schlador
Title:	President
Telephone:	208.939.3447
Fax:	208.939.3448
Email:	fs@regulatoryresources.com

3.2 Device Identification

Trade Name:	I-PORT™
Regulation Name:	Intravascular Catheter
Common Name:	Catheter, Intravascular, Short-Term
Regulation Number:	21 CFR 880.5200
Device Classification:	Class II
Product Code:	FOZ

3.3 Predicate Devices

- Unomedical, Inc. Insuflon™, Intravascular Catheter (K881767)
- Medtronic MiniMed Paradigm® Sof-set® Infusion Sets (K030149)

3.4 Device Description

The I-PORT™, Injection Port is a sterile, single use, low profile injection port through which physician prescribed medications can be injected subcutaneously from a standard syringe and needle, pen or alternative manual injection device. The device is designed to reduce the hardships of multiple daily subcutaneous injections by allowing users to receive physician prescribed medication, including insulin, without repeated needle punctures of the skin.

The I-PORT™, Injection Port may remain in place for up to 72 hours to accommodate multiple drug injections without additional needle sticks.

3.5 Intended Use

The I-PORT™, Injection Port is a disposable, low profile, injection port through which physician prescribed medications, including insulin, can be injected subcutaneously from a standard syringe and needle, pen or alternative manual injection device. The I-PORT™, Injection Port allows users to manually inject physician prescribed medication without repeated needle punctures of the skin over a 72 hour time period.

The intended environments include home use and use in health care facilities.

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3.6 Indications for Use

The I-PORT™, Injection Port is indicated for patients who administer, or to whom is administered, multiple daily subcutaneous injections of physician prescribed medications, including insulin.

This device may be used on a wide range of patients, including adults and children.

3.7 Performance Data and Comparison of the I-PORT™, Injection Port to Predicate Devices

The I-PORT™, Injection Port and the predicate devices have similar, and in many cases, the same:

- Intended use and indications for use
- Principals of operation
- Dimensional and mechanical characteristics
- Performance characteristics
- Components and materials

Laboratory testing verified that the performance of the I-PORT™, Injection Port met both internal specifications and user needs. Representative samples of the device underwent bench testing to verify functional and performance characteristics.

3.8 Risk Management

Risk Management activities included the identification and evaluation of risks associated with the use of this device. Fault Tree Analysis (FTA) and Failure Modes and Effects, and Criticality Analysis (FMECA) were conducted. No risks that are not common to the use of this type of device were identified. All of the identified risks reside in the As Low as Reasonably Practicable (ALARP) and/or Broadly Acceptable regions.

3.9 Biocompatibility

Materials used in the I-PORT™, Injection Port are biocompatible. These materials meet the requirements of **ANSI/AAMI/ISO 10993-1:2003** Biological Evaluation of Medical Devices – Part 1:Evaluation and Testing for a prolonged body contact, external communicating device and/or contain the same components used in a similar legally marketed device.

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3.10 Compliance with Guidance and Consensus Standards

The I-PORT™, Injection Port conforms to relevant portions of applicable guidance and standards that include the following:

- **ISO 10555-1:1995** Sterile – Single-use Intravascular Catheters Part 1:General Requirements
- **ANSI/AAMI/ISO 10993-1:2003** Biological Evaluation of Medical Devices – Part 1:Evaluation and Testing
- **ANSI/AAMI/ISO 14971:2000** Medical Devices – Application of Risk Management to Medical Devices
- **ANSI/AAMI/ISO 14971/A1:2000** Medical Devices – Application of Risk Management to Medical Devices – Amendment 1:Rationale for Requirements
- **ANSI/AAMI/ISO 11607:2000** Packaging for Terminally Sterilized Medical Devices
- **ANSI/AAMI/ISO 11135:1994** Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization, 3ed
- **ANSI/AAMI/ISO 10993-7:1995** Biological Evaluation of Medical Devices – Part 7:Ethylene Oxide Sterilization Residuals
- **ASTM F1929-98(2004)** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- **ASTM F1980:2002** Standard Guide for Accelerated Aging of Sterile Medical Device Packages
- **ASTM D4169-04a** Standard Practice for Performance Testing of Shipping Containers and Systems
- **ASTM F88-05** Standard Test Method for Seal Strength of Flexible Barrier Materials

3.11 Sterilization

The I-PORT™, Injection Port will be sterilized using Ethylene Oxide (EO). The sterilization process will be conducted following appropriate AAMI/ANSI/ISO Guidelines.

The I-PORT™, Injection Port will have a SAL of 10^{-6} and the fluid path will be Pyrogen free as tested by limulus amebocyte lysate (LAL). The packaging will be tested to applicable standards to ensure integrity and durability.

3.12 Conclusion

The I-PORT™, Injection Port is substantially equivalent to the relevant aspects of the predicate devices in terms of principals of operation, mechanical characteristics, performance characteristics and components and materials. The understanding of the application and use of the I-PORT™, Injection Port by healthcare professionals and potential users make the I-PORT™, Injection Port equivalent to or easier to use than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

Patton Medical Devices
c/o Ms. Laura Danielson
TUV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K052389
Trade/Device Name: I-Port
Regulation Number: 880.5220
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: August 30, 2005
Received: August 31, 2005

Dear Ms. Danielson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Aso, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K452339

2.0 INDICATIONS FOR USE

Device Name:

I-PORT™, Injection Port

Indications for Use:

The I-PORT™, Injection Port is indicated for patients who administer, or to whom is administered, multiple daily subcutaneous injections of physician prescribed medications, including insulin. The I-PORT™, Injection Port may remain in place for up to 72 hours to accommodate multiple drug injections without the discomfort of additional needle sticks.

This device may be used on a wide range of patients, including adults and children.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 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)

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

510(k) Number: K452339