CENTURION
MEDICAL PRODUCTS

JUN 23 2011

510(k) Summary

Manufacturer:	Centurion Medical Products Corporation 100 Centurion Way Williamston, MI 48895
Contact:	Mr. Matthew K. Price Director of Quality Assurance and Regulatory Affairs Phone: (517) 546-5400, x1135 Facsimile: (517) 546-3356
Date Summary Prepared:	November 29, 2010
Trade Name (Proprietary Name):	Centurion® Pressure Injectable Extension Set
Common Name of Device:	Intravascular Administration Set
Classification Name:	Set, Administration, Intravascular
Device Classification:	II
Regulation:	880.5440
Product Code:	FPA
Review Panel:	General Hospital
Reason for 510(k):	Marketing of Centurion® Pressure Injectable Extension Sets for Physician and Hospital use.

Predicate SE Device(s):

This product is similar in design, composition, function, and method of use to the following products:

- Cardinal Health, Alaris ® Products, SmartSite® Needle Free Valve Administration Sets (K061285)

Description:

The Centurion® Pressure Injectable Extension Set is an IV extension set intended for the delivery and/or aspiration of fluids and may be used in conjunction with power injectors having a maximum pressure setting of 325 psi and a maximum flow rate of 10 mL/second.

Centurion® Pressure Injectable Extension Sets consist of polyvinyl chloride (PVC) tubing with non-DEHP plasticizer. They are configured with female luer locks and male luer locks on the proximal and distal ends, respectively, and are available in straight, Y, and T configurations. A slide or snap clamp may be positioned over the tubing to obstruct the fluid flow when needed.

The Centurion® Pressure Injectable Extension Set is available in configurations with and without a needle-free valve. These valves are separately marketed devices and the applicable 510(k)'s are maintained by the respective manufacturers.

The Centurion® Pressure Injectable Extension Sets are prescription devices provided sterile and non-pyrogenic for single use only and may be packaged individually or in medical convenience kits.

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phone 517.546.5400 | toll free 800.248.4059 | www.centurionmp.com

Intended Use:

Centurion® Pressure Injectable Extension Sets are prescription devices intended to allow the aspiration, injection, or gravity/pump flow of fluids and may be used with power injectors having a maximum pressure setting of 325 psi. When used with a power injector, the Centurion® Pressure Injectable Extension Set must be secured to other devices, via a luer lock connection. These devices must also be rated for power injection applications.

Summary of Technological Characteristics between Subject and Predicate Device:

The differences in technological characteristics (e.g., design specifications) between the subject and predicate devices raise no new questions of safety or effectiveness. Slight differences in materials, dimensions, sterilization method, and warnings exist; however, these differences do not affect the safety and effectiveness of the subject device.

Performance Data:

The results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the Centurion® Pressure Injectable Extension Set are sufficient for its intended use and support a determination of substantial equivalence.

Summary of Testing:

Biocompatibility testing was performed on Centurion® Pressure Injectable Extension Sets in accordance with ANSI/AAMI/ISO 10993-1:2009: *Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing* and *AAMI Standards and Recommended Practices, Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices.* Results of testing validate Centurion® Pressure Injectable Extension Sets are non-cytotoxic, non-sensitizing, a negligible irritant, non-hemolytic, and a low potential activator of the complement system.

Centurion® Pressure Injectable Extension Sets will be available only in sterile packaged form. The sterile product will be sterilized using ethylene oxide. The sterilization method was validated and performed in accordance with ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.* A sterility assurance level of 1×10^{-6} has been validated for this product.

Centurion's packaging has been validated for performance and shelf life in accordance with ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*

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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

Mr. Matthew K. Price
Director of Quality Assurance & Regulatory Affairs
Centurion Medical Products Corporation
100 Centurion Way
Williamston, Michigan 48895

JUN 23 2011

Re: K103562
Trade/Device Name: Centurion® Pressure Injectable Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 15, 2011
Received: June 16, 2011

Dear Mr. Price:

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/ucm 115809.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,

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

K103562

CENTURION
MEDICAL PRODUCTS

Indications for Use Statement

510(k) Number (if known):

Device Name: Centurion® Pressure Injectable Extension Set

Indications For Use:

The Centurion® Pressure Injectable Extension Set is an IV extension set intended for the delivery and /or aspiration of fluids and may be used in conjunction with power injectors having a maximum pressure setting of 325 psi and a maximum flow rate of 10 mL/second.

Contraindications:

Contraindicated for use with blunt cannulae systems.

Cautions:

1. For unattended medication delivery use only a luer-locking I.V. set or syringe.

2. Refer to the Centurion pressure injectable valve information sheet for applicable valve pressure rating and valve instructions.

3. When used with a power injector, the Centurion Pressure Injectable Extension Set must be secured to other devices via a luer lock connection. These devices must also be rated for power injection applications.

4. Centurion Pressure Injectable Extension Sets are intended for use with power injectors under the following conditions:
   a. Before attempting power injection, ensure patency and that any unused access ports are securely capped.
   b. All components (from injector to catheter) must be rated for use with a power injector at the selected pressure setting.
   c. A 20-gauge or larger IV catheter should be used.
   d. A minimum 60" coiled connector tubing must be used between the injector syringe and Centurion set.
   e. The injector pressure limit must be set to 325psi or below and the flow rate set to a maximum of 10mL/second.

Warning:

Do not use this product with pressure infusion systems at a pressure setting above 325 psi.

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

6/23/4

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