DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 19, 2015

Busse Hospital Disposables
Mr. Muhamad Ansari
Director of Regulatory Affairs
75 Arkay Drive
Hauppauge, NY 11788

Re: K141285
Trade/Device Name: Busse Extension Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: January 15, 2015
Received: January 20, 2015

Dear Mr. Ansari:

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" (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 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 yours,

Tina Kiang -S

for Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K141285

Device Name
Busse Extension Set

Indications for Use *(Describe)*
Busse Extension Sets are intended to be used with a vascular access device for administrative and withdrawals of fluids.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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K141285

510(k) Summary

Regulatory Affairs Contact:	Muhamad Ansari Busse Hospital Disposables 75 Arkay Dr. Hauppauge NY 11788
Telephone:	631-435-4711 Ext: 254
Fax:	631-435-2849
Date Summary Prepared:	May 7, 2014
Product Trade Name:	Busse Extension Set
Common Name:	Intravascular Administration Set
Classification Name:	Class II, 21 CFR 880.5440, Product code FPK and FPA
Predicate Device:	Centurion Pressure Injectable Extension Set, Centurion Medical Products, K103562
Device Description:	Busse Extension Set consists of PVC tubing with or without connectors. The tubing accessories include; 3-way connectors, clamps, male and female luer lock, luer slip fitting, and valves. The Extension Set will be provided as sterile, single use only and will be packaged individually and in medical convenience kits. The Extension Sets will be available in a variety of lengths, starting from 6" to 36".
Intended Use:	Busse Extension Sets are intended for use with a vascular access device for administration and withdrawal of fluids.

Technological Characteristics:

The subject device has the same Technological Characteristics as a legally marketed predicate device. Below is summary of Technological Characteristics as compared to the Predicate Device.

Technological Characteristics	Proposed Device	Centurion Medical Products
Intended Use	Intended for use with a vascular access device for administration and withdrawal of fluids	Intended to allow the aspiration injection, or gravity/pump flow of fluids
Labeling	21 CFR Part 801	21 CFR Part 801
Biocompatibility	ISO 10993-1	ISO 10993-1
Sterilization	ISO 11135-1 Ethylene oxide	ISO 11135-1 Ethylene oxide
Sterility Assurance Level	10^{-6}	10^{-6}
Product Name	Busse Extension Set	Centurion Pressure Injectable Extension Set
Packaging	ISO 11607-2	ISO 11607-1
Material	PVC	PVC

This type of device has been marketed in the Unites States for many years, using the same materials used by the Extension Sets, and no issues of safety and effectiveness have been raised.

Summary of Testing:

All materials used in the fabrication of the Busse Extension Sets were evaluated through biological qualification safety tests.
The biocompatibility tests performed were:

- L929 MEM Elution Test
- Kligman Maximization Test
- Intracutaneous Injection Test
- Systemic Injection Test
- Rabbit Pyrogen Test
- Hemolysis Test

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Summary of Performance Testing: Busse Extension Sets has been tested for the following performance tests:

- Liquid Leakage
- Pull Test
- Durameter Test
- Conical Fitting

These materials have met the testing requirements and were found to be acceptable for the intended use.

Conclusion: The above statements are accurate representations of the device Busse intents to market. Based on all the testing and comparison Busse believes the subject device is substantially equivalent to the predicate device. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.

Official Correspondent: Muhamad Ansari (Signature)

Muhamad Ansari (printed name)

Title: Director of Regulatory Affairs

Date: 2/19/2015