K100705

Appendix G Summary of Safety and Efficacy

510(K) SUMMARY

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Date Originated: March 5, 2010
Trade Name: Z-800 Infusion System
Common Name: Volumetric Infusion Pump
Classification Name: Infusion Pump
Product code: FRN 880.5725

Predicate Devices
-Z-800 Infusion pumps (K071545)
-B. Braun Vista basic (formerly known as Infusomat P, K003029)
-Sigma 8000 (K950766)
-Abbott Acclaim Encore (K991501)

Intended Use

The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a human patient under the direction or supervision of physician or other certified health care professional.

Device Description:

The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a human patient under the direction or supervision of physician or other certified health care professional.

The Z-800 Infusion System consists of the Z-800 Infusion Pump and approved external IV administration sets. The scope of this 510K is to qualify CareFusion's blood administration sets

(K882302) for use with the currently marketed Z-800 infusion pump system so as to extend the intended use of the Z-800 Volumetric Infusion Pumps to include intravenous administration of blood and blood products. The infusion pump remains the same as currently marketed Z-800 infusion pump, as in the predicated device Z-800 infusion system (K0717545).

The Z-800 infusion system contains the following components:

- The infusion delivery mechanism: Volumetric linear peristaltic pumping mechanism assembly.
- Approved IV administration sets include External IV sets for intravenous parenteral fluid delivery and for intravenous blood and blood product delivery.
- User Interface consists of a 128 X 64 dot matrix LCD display; a 14 key membrane keypad; a LED flow rate display; two device status indicator LEDs; power status indicator LEDs (AC & Battery); an audio speaker; an external alarm light accessory; an software alarm handler.
- The embedded software on the main CPU execute an infusion pump state machine, which monitors the execution of currently programmed infusion as well as a collection of safety related alarm conditions.
- A watchdog timer is set at 50ms interval. Fail to satisfy the watchdog timer will cause both main CPU and motor control CPU reset, pump device parks at a fail safe state, and an audible alarm to sound.
- Power supply consists of AC/DC power. Z-800 infusion pump is intended to be used as a pole mounted pump. It contains a medical device grade switch power supply (input 100-240V 50-60Hz, 0-1.4A, output 15vdc) and a rechargeable 4700mA, 8X1.2 volt Nickel Metal Hydride battery pack. A fully charged new battery will power at least 8hr of continuous infusion (at 125mL/hr). A full battery charging time on a new battery is around 5hr. The battery charging circuitry has a dedicated controlling CPU, which manages the charging current as well as the battery safety monitoring. Redundant temperature sensor is embedded in the battery pack capable of shut off the charging current if battery pack temperature is above the safety threshold.
- There is 128K flash EPROM memory which stores the embedded software along with 8K NVRAM for user specified configuration as well as preserving infusion parameters between power cycles.
- Z-800 infusion pump uses linear peristaltic pumping mechanism driven by a step motor through driving belt. The ID/OD, wall thickness and the durometer of the IV set are specified by Zyno to the IV set manufacturers to ensure the accuracy specification of flow rate.
- The user interface design requirement of the Z-800 pump is focused on simplicity and intuitiveness. The keypad contains 3 groups of keys: the navigation key group; the data entry key group; and the action key group. There is no numeric data entry keypad. All data entry keys are scroll key. This design is to focus user's attention to the data entry results on the display while entering the infusion parameters, so as to mitigate data entry error caused by key bounce or user hitting the wrong keys.
- The Z-800 infusion pump has an all metal casing to improve the durability of the pump and the integrity of the pumping/free flow protection mechanism. The pump door and the mating pump front panel are made in milled aluminum. The tubing guide cavity is designed to mitigate tubing loading error. If the tubing is not loaded correctly, the door can not be closed. Even user jam close the door, the mating pump door and the front panel will shut off the tubing to prevent free flow, and the drip sensor accessory will report no flow to alert user of misloaded tubing.

- There is no known contraindication.

The equivalency matrix (Table 1) compares the Z-800 Infusion pump with the predicate devices.

Table 1: Equivalency Matrix

Parameter	Z-800	B. Braun Vista basic	Sigma 8000	Abbott Acclaim Encore
Pump Type	Volumetric Infusion Pump	Volumetric Infusion Pump	Volumetric Infusion Pump	Volumetric Infusion Pump
Intended use	Intra-venous	Intra-venous Enteral	Intravenous Epidural	Intravenous Enteral
Units of delivery	ml/hr	mg/kg/min mg/kg/hr mg/min mg/hr mcg/kg/min mcg/kg/hr mcg/min mcg/hr g/kg/hr g/hr g/kg/min g/min U/kg/hr U/kg/min U/min U/hr ml/hr ml/min	units/hr units/kg/min units/kg/hr milliunits/min grams/hr mcg/kg/min mcg/kg/hr mcg/min mcg/hr mg/kg/min mg/kg/hr mg/min mg/hr ml/hr	ml/hr mcg/min mcg/kg/min
Pumping mechanism	Linear peristaltic pump	Linear peristaltic pump	Linear peristaltic pump	Linear peristaltic pump
Free Flow Protection	IV set based free flow protection (Option) Pump based free flow protection YES	IV set based free flow protection (Option) Pump based free flow protection YES	IV set based free flow protection YES. Pump based free flow protection YES	IV set based free flow protection YES. Pump based free flow protection YES
Administration sets	Approved standard PVC gravity tubing	B. Braun basic pump administration sets.	Approved standard PVC gravity tubing	Approved standard PVC gravity tubing
Power source	AC: 100-250V 50-60 Hz DC: Internal Nickel Metal Hydride	AC: 100-120V 50-60 Hz DC: Internal NiCd	AC: 105-135V 50/60 Hz 220-240V 50/60 Hz DC: Sealed lead acid	AC: 100-130V 47-63 Hz DC: Internal rechargeable 8V battery
Battery Life	8 hours at 125 ml/hr	3 hours at 125 ml/hr,	5 hours	8 hours at 125ml/hr
Display	Program controlled dot matrix LCD	Custom LCD	LED	Custom LCD
Case construction	Milled Aluminum & Sheet Metal Enclosure	Sheet Metal and Injection Molded Plastic Enclosure	High impact Injection Molded Plastic Enclosure	High impact Injection Molded Plastic Enclosure
Size (inch)	8.6H x 5.7W x 5.3D	9.4Hx 5.5W x 7.8D	9.5Hx 6.5Wx 6.75D	8.25Hx7Wx5.74D
Weight	5.7 lbs	6.8 lbs.	10 lbs	7 lbs
Volume and Rate Accuracy	+/- 5%	+/- 5%	+/- 5%	+/- 5%
Occlusion Pressure Accuracy	Low: 4 psi Medium 16 psi High: 30 psi adjustable	Low: 8 psi, unspecified accuracy High 17 psi, unspecified accuracy	Low 2 psi High 15 psi adjustable	Low 6 psi Medium 10pis High 20 psi

Parameter	Z-800	B. Braun Vista basic	Sigma 8000	Abbott Acclaim Encore
Rate Range	1ml/hr to 999 ml/hr in 1ml/hr increment	0.1 to 800 ml/hr	0.1 to 99.9 ml/hr (in 0.1 ml/hr increments) 100 to 999 ml/hr (in 1 ml/hr increments)	1.0 to 99.9 ml/hr (in 0.1ml/hr increments) 100 to 999 ml/hr (in 1 ml/hr increments)
Warnings / Status	Low Battery Near End Infusion Complete Pump unattended KVO	Low Battery Near End Infusion Complete Pump Stopped Bag Empty (with Drip Sensor) KVO	Low battery Improper IV set loading Infusion Complete Close Roller Clamp PM Due KVO	Battery Check Settings VTBI complete Stopped (unattended) No Slide Clamp KVO
Alarms	Occlusion Battery Empty Air-In-Line Door Open System Error No Drip (with drip sensor) Drip sensor connection (with drip sensor)	Occlusion Plug In Now Air-In-Line Door Open Unit Malfunction	Occlusion Plug in Air-In-Line Pump Malfunctions	Occlusion Battery Off Air-In-Line Check Door Check Slide Clamp
Inputs	Continuous Mode Primary Rate Primary VTBI Secondary Rate Secondary VTBI Volume/Time Primary VTBI Primary Time Secondary VTBI Secondary Time TPN Total VTBI Total Time Ramp Up Time Ramp Down Time 10 Step Sequence N^{th} Rate N^{th} VTBI (N=1 to 10)	Continuous Mode Primary Rate Primary VTBD Secondary Rate Secondary VTBD Volume/Time Primary VTBD Primary TIME Secondary VTBD Secondary TIME Rate & Time Primary Rate Primary Time Secondary Rate Secondary Time TPN Total Bag Volume Total Time Ramp Up time Taper Down Time 10 Step Sequence N^{th} Rate N^{th} VTBD (N=1 to 10) Dose Calc Mode Concentration Value Concentration Unit Body Weight Drug Dose amount Drug Dose Unit Diluent Volume Delay A Mode Delay Time Amount Standby Time Amount	Continuous Mode Primary Rate Primary VTBI Piggyback Rate Piggyback VTBI Volume/Time Primary VTBD Primary TIME Piggyback VTBD Piggyback TIME Rate & Time Primary Rate Primary Time Piggyback Rate Piggyback Time TPN Volume Limit Main Rate Ramp Time Taper Time 21 Step Sequence N^{th} Rate N^{th} VTBI (N=1 to 21) Dose Rate Mode Drug Dose amount Drug Dose Unit Body Weight Diluent Volume Volume Limit Delay Start Mode Delay Time Amount KVO option	Continuous Mode Primary Rate Primary VTBI Secondary Rate Secondary VTBI Volume/Time Primary VTBI Primary TIME Secondary VTBI Secondary TIME TPN Total VTBI Total TIME Taper up TIME Taper down TIME Dose Calc for MICROGRAM delivery Patient Weight Drug amount Diluent Volume Dose Rate

Parameter	Z-800	B. Braun Vista basic	Sigma 8000	Abbott Acclaim Encore
Serial Communications	Bidirectional	Bidirectional	Bidirectional	None

System validation for the Z-800 Volumetric Infusion Pump was performed according to the Z-800 System Validation Plan in compliance with the FDA guidance "Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions *(DRAFT GUIDANCE)* issued in April 23, 2010, and Zyno Medical's Quality Development Procedure. Assurance case report has been generated to demonstrate there is no incremental risk to patient and user safety as well as to the Z-800 infusion system efficacy has been introduced by qualifying CareFusion blood IV set (K882302) to be used with Z-800 infusion pump device. Hemolysis was identified as incremental potential risk. As a result of this risk analysis assessment, flowing blood hemolysis test with human blood was performed using production units which are identical to the currently marketed Z-800 infusion pumps. Per Zyno Medical LLC request, the test was conducted by a certified lab according to recognized Good Laboratory Practices following FDA recognized ASTM standard for assessment of hemolytic properties. All acceptance criteria were met (Each blood sample had a plasma free hemoglobin level that is less than 2 mg/mL; the correlation coefficient for the hemoglobin standard curve is greater than 0.95). Risk management activity has been incorporated into the device design/development process. A risk management report has been compiled to document risk level assessment for the list of FDA identified risks for infusion pump systems in Appendix A of "Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions *(DRAFT GUIDANCE)* issued in April 23, 2010. Z-800 Validation Summary Report TR800-2010-02 submitted in Appendix E summarized the validation test results, which supports the conclusion which indicates that adding CareFusion blood set (K882302) to be used with Z-800 infusion pump for intravenous delivery of blood and blood products does not introduce any incremental risk to the user/patient safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
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JUL - 8 2010

Re: K100705
Trade/Device Name: Zyno Z-800 Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Dated: June 8, 2010
Received: June 10, 2010

Dear Mr. Lee:

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,

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 (if known): _____

Device Name: Z-800 Volumetric Infusion System

Indications for Use: The Z-800 Infusion system is intended to provide intravenous infusion of parenteral fluids, blood and blood products to a human patient under the direction or supervision of physician or other certified health care professional.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/8/10

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

510(k) Number: K100705