



510(K) SUMMARY

1. Submitter Information

Bridge Medical, Inc.
265 Santa Helena Suite 210
Solana Beach, CA 92075

09/09/97

Contact Person: Donald V. Canal
Director Product Development and Manufacturing
Phone: (972) 964 - 6740
FAX: (972) 964 - 7524

2. Name of Device

Trade/Proprietary Name: Bridge Sentry™ Bedside Unit, Bridge Sentry Pharmacy Utility and Bridge Sentry Administration Sets (collectively referred to as the Sentry System).
Common/Usual Name: External Infusion Pump and Administration Set
Classification Name: Infusion Pump; Intravascular Administration, Set, Compounder

3. Predicate Devices

The predicate devices are shown in the table below:

MANUFACTURER / DEVICE NAME	510(K) NUMBER
PRYOR Patient Pal IV Walker	K820963 procode FOX
Medical Specialties, Inc./ Infusion Stand	K946201 procode FOX
River Medical, Inc./ SmartDose Drug Vial Adapter	K933335 procode FRN
McGaw, Inc./ ADD-A-VIAL II Binary Connector	K900865 procode LHI
BAXA, Inc. / MicroMacro 12 Compounder	K904225 procode LHI

Bridge Medical, Inc.
265 Santa Helena, Suite 210, Solana Beach, California 92075
Tel: 619 350 0100 Fax: 619 350 0115

MANUFACTURER / DEVICE NAME	SKU/KNUMBER
IVAC, Inc. / Controlled Release Infusion System(CRIS)	K852488 procode FPA
Abbott Laboratories, Inc. / Therapist Infusion System 4000 (OmniFlow)	K900467 procode FRN
McGaw, Inc./ Volumetric Infusion Pump and IV Set.	K904518 procode FRN

The Bridge Sentry™ Bedside Unit includes six functions which are listed below with the appropriate product code:

- 1) Infusion Pump - The Bridge Sentry Bedside Unit has the capability to control the delivery of IV drugs to the patient. These drugs may be standard IV drugs and solutions, pharmacy admixtures and drugs that require reconstitution, and dilution. (21 CFR 880.5725 'Infusion Pump'. Procode FRN)
- 2) Fluid Delivery - The Bridge Sentry™ Administration Sets perform the fluid delivery. (21 CFR 880.5440 'Intravascular Administration Set'. Procode FPA)
- 3) Vial access/Reconstitution - The Bridge Sentry Bedside Unit provides access for fluid to transfer from a diluent source to a drug vial. Reconstitution is the process of dissolving a lyophilized or powdered drug into a diluent. (21 CFR 880.5440 'Intravascular Administration Set'. Procode LHI - 'Fluid Transfer Device')
- 4) Mixing - The Sentry performs fluid transfer in order to mix two fluids into a homogeneous concentration. (21 CFR 880.5440 'Intravascular Administration Set'. Procode LHI - 'Fluid Transfer Device')
- 5) Rinse/Flush - The Sentry has the capability to rinse/flush the fluid path to allow sequential rinsing/flush and delivery of multiple drug doses through the same disposable to minimize the possibility of drug interactions. (21 CFR 880.5440 'Intravascular Administration Set'. Procode FPA)
- 6) Infusion Stand - The Sentry contains an IV pole to be used for mounting and transporting IV pumps. (unclassified pre-amendment product. Procode FOX 'Infusion Stand')

4. Description of the Subject Device

The Bridge Sentry™ Bedside Unit, The Bridge Sentry Pharmacy Utility and the Bridge Sentry™ Administration Sets are collectively referred to as the Sentry System. The Sentry System includes an electrical, external, volumetric drug compounder and infusion pump. The administration sets contain a dedicated cassette that is compatible with the Bridge Sentry Bedside Unit.

The Sentry is an electro-mechanical device incorporating a sterile disposable cassette with ancillary fluid delivery tubing and components. The Sentry stores drug delivery preset information for reconstitution, dilution and delivery. These presets are based on industry standards derived from drug labeling. The preset information is downloaded into each Sentry device. The Sentry requires identification of the patient, the user, the drug, and the diluent as part of the setup operation. The identification may be accomplished via bar code scan or menu selection. The Sentry uses the identification information in conjunction with the pharmacy presets to minimize errors and capture drug event information.

The Sentry System provides accurate and continuous flow of fluids to the patient. The device operates using a proprietary Acoustic Volume Sensor, a form of actuation pressure and a precision fluid impedance in the set to for a closed loop flow control system. The system detect occlusions in the patient line downstream and determines if sufficient fluid can be drawn from an upstream source to continue patient delivery. The system also detects air in line and when possible eliminates the air.

The administration sets are sterile, and for single patient use. The Administration Sets are composed of a unique cassette and various combinations of other standard administration set components including tubing, filters, spikes, drip chambers, injection sites, clamps, caps or protectors, and luer connectors.

The Sentry Cassette contains 10 valves to control fluid flow, a precision control orifice for flow control, a front cover, rear cover, mid-body, an inlet port, outlet port, a luer connection, and three drug vial spikes.

The Sentry device contains a System Management Module, a Fluid Delivery Module, bar code scanner, infusion stand base and pole(s), vial attachment mechanism, battery, pharmacy utility, air in line sensor, and a data acquisition computer.

The solution contact materials are listed in Table 1 below:

Table 1 - Solution Contact Components

Material	Chemical Name
Monsanto LUSTRAN ABS 248-2002 White Resin,	Acrylonitrile-Butadiene-Styrene
BASF Terluc 2802 TR Transparent (equivalent nomenclature 2802 TR Q161) ABS, Methyl Methacrylate/ Acrylonitrile/Styrene/Butadiene Polymer	
Himont PROFAX PD-626 Polypropylene	
Advanced Elastomer System's Santoprene Thermoplastic Rubber, Medical Grade 281-64	
Advanced Elastomer System's Santoprene Thermoplastic Rubber, Medical Grade 281-64	
Advanced Elastomer System's Santoprene Thermoplastic Rubber, Medical Grade 281-64	
Advanced Elastomer System's Santoprene Thermoplastic Rubber, Medical Grade 281-64	
Monsanto LUSTRAN ABS 248-2002 White Resin,	Acrylonitrile-Butadiene-Styrene
BASF Terluc 2802 TR Transparent (equivalent nomenclature 2802 TR Q161) ABS, Methyl Methacrylate/ Acrylonitrile/Styrene/Butadiene Polymer	
Dow Corning 360 Medical Fluid, 100 cs Viscosity,	Polydimethylsiloxane

Device Specifications:

Flow Rates: 1.0 - 1000.0 ml/hr

Volume To Be Infused: 0.1 to 9999.9 ml

Volumetric Accuracy: +/- 5 percent

Battery: 12 Volt - 10 amp hour sealed lead acid

Battery Infusion Time: 4 hour at 100 ml/hr

Occlusion Pressure: 150 mmHg and 500 mmHg

Fluid Types: All standard IV drugs (Excluding Blood, Blood Products and Medications containing Lipids)

5. Intended Use

The Bridge Sentry™ System is intended for controlled intravenous delivery and mixing (as required) of drugs. The Bridge Sentry System is also intended for the preparation (reconstitution, as required, and mixing) of single dose, intermittent, anti-infective and gastrointestinal drugs.

6. Technological Characteristics

The Sentry System is substantially equivalent to the predicate devices. The differences are in the areas of the fluid movement and monitoring, and

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electronic control of processes that are performed manually by the predicate devices. Refer to Table 2 for a list of differences between the subject device and the predicate devices.

Table 2 Technological Differences

Vial Access/ Reconstitution	pneumatic agitation	manual - squeeze, shake
Mixing	pneumatic agitation with acoustic volume sensing (AVS) volumetric control	gravity, rotary peristaltic with volumetric control
Infusion Pump	Pneumatic actuation with AVS volumetric control	Bellows actuated diaphragm with volumetric control (Horizon) Piston Actuated with volumetric control (OmniFlow)
Rinse/Flush	pneumatic agitation with acoustic volume sensing (AVS) volumetric control	gravity with a known volume (CRIS) rotary peristaltic with control volume (BAXA) Piston Actuated with volumetric control (OmniFlow)
Fluid Contact Materials	Refer to Table 1	Refer to Table 1

7. Performance Test Data Summary

Test data has been included in the application to demonstrate substantial equivalence of the Sentry System. Table 3 contains a summary of the test method, criteria and test results.

Table 3 - Performance Testing to Support Substantial Equivalence

Reconstitution	USP<1> Constitution USP<851> Spectrophotometry	Manual reconstitution methods according to the drug manufacturers guidelines are used as the control to show that the Sentry System is equivalent or better.	Equivalent
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Mixing	USP Drug Assay utilizing High Performance Liquid Chromatography (HPLC) to measure the concentration accuracy of the mixture	Concentration consistency is within 10 percent throughout a 50 ml mix cycle and mass balance of drug is \geq 95 percent.	Equivalent
Delivery	AANSI/AAMI ID26-1992 guidelines for infusion devices	The Sentry will conform to the ANSI/AAMI specification which is equivalent or better than the delivery performance of the predicates: Horizon Nxt and the OmniFlow 4000.	Equivalent
Rinse/Flush	USP Trace Drug Assay High Performance Liquid Chromatography (HPLC) to measure the residual drug concentration	reduction in concentration is \geq 97 percent	Equivalent
Solution Contact Materials	ISO10993 Standard Physicochemical Tests: Elastomers and Physicochemical Tests: Plastics	Acceptable results from standard tests	Equivalent

8. Substantial Equivalence Conclusion

The substantial equivalence claim between the Sentry System and the predicate devices is supported by the descriptive information and performance testing of the Sentry system, which met the criteria for predicate equivalence for all functional areas.

9. Signature of Applicant

Bridge Medical, Inc.
Donald V. Canal
Director Product Development and Manufacturing

Signature:  Date: 9/9/97



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald V. Canal
Director of Manufacturing and Product Development
Bridge Medical, Incorporated
265 Santa Helena, Suite 210
Solana Beach, California 92075

Re: K973593
Trade Name: Bridge Sentry Bedside Unit, Bridge Sentry™
Administration Set
Regulatory Class: II
Product Code: ERN
Dated: July 21, 1998
Received: July 23, 1998

Dear Mr. Logan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

S. Antman for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications For Use Statement

510(k) Number (if known): K973593

Device Name: Bridge Sentry™ System

Indications For Use:

The Bridge Sentry™ System is intended for the infusion (or administration) of fluids or medications. It is also intended for the preparation (reconstitution, as required, and mixing) of single dose, anti-infective and gastrointestinal drugs. It is not intended for use with blood, blood products or lipids.

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Over-The-Counter Use

[Handwritten Signature]

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

510(k) Number K973593

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