APR 12 2012 K120209

CONFIDENTIAL

510(k) Summary

This product is not sterile, has no software component, has no electronic components and is not a kit.

Device Name

AIV Device Name:	**Patient Pendant Bolus Cable**
Classification Name:	Patient Controlled Analgesia (PCA) Button Cables
Common Name:	Bolus Cables

Applicant

American IV Products, Inc.
7485 Shipley Avenue
Harmans, MD 21077

Submittal Date

January 17, 2012

Contact Name

Majdi F. Shomali
VP – Engineering
(410)787-1300 Ext. 131

Establishment Registration Number

1121996

Device Classification

Device Regulation Number	21 CFR 880.5725
Regulation Name	Pump, infusion
Class	Class II
Product Code:	MRZ - Accessories, pump, infusion

514 Performance Standards

None established under section 514

Prescription Status

The subject devices are a prescription device.

Compliance to Standards and Regulations

EN ISO 14971:2007 Medical devices – Application of Risk Management to Medical Devices

Reason for Submission

This is a new device to be marketed by our firm.

Labeling

Proposed labeling is provided in Section C.

Statement of Indications for Use

This device is an accessory for a syringe or infusion pump (not manufactured by AIV, Inc.). The healthcare worker connects the device to the corresponding pump. The patient uses the switch on the cable to signal the pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker.

AIV Part #	Infusion / Syringe Pump
BC10746	Baxter I Pump
BC10747	Baxter PCA II
BC10925	Abbott / Hospira PCA 3
BC10969	Abbott / Hospira Lifecare 4100 PCA Plus II

Product Description

AIV's **Patient Pendant Bolus Cables** are a replacement for similar cables manufactured by the Original Equipment Manufacturers (OEM) for their respective syringe and infusion pumps. AIV does not manufacture the pumps. These **Patient Pendant Bolus Cables** are an accessory for the pump and are also available as a replacement part. These cables include a switch and are plugged into a mating connector on the syringe or infusion pump to allow the patient to request medication within the parameters entered into the syringe pump by the healthcare provider and the designed limits on the pumps.

The AIV **Patient Pendant Bolus Cables** use the same type of construction and have the same technological characteristics as the predicate device – the accessory supplied with the original pump. These are passive devices that contain no electronic components. They are powered by the mating equipment using low voltages to detect changes in the state of the push button. Shielding and insulation of these devices is substantially equivalent to the predicate device.

AIV **Patient Pendant Bolus Cables** use Biocompatible PVC for the cables, cable jackets and over molded connectors with an integral strain relief. (See Section F for biocompatibility test reports)

The AIV **Patient Pendant Bolus Cables** are limited by the indications for use of the connected syringe pump equipment.

Section D contains product drawings and wiring diagrams.

Predicate Device Information

These AIV devices are Substantially Equivalent to the accessory available with the following legally marketed devices:

BAXTER HEALTHCARE CORP.	K052973, K993387
ABBOTT LABORATORIES	K022203

Substantial Equivalence Comparison Chart

AIV		Baxter	Abbott
Intended Use	This device is an accessory and a replacement part for a syringe or infusion pump (not manufactured by AIV, Inc.). The healthcare worker connects the device to the corresponding pump. The patient uses the switch on the cable to signal the pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker and limitations set by the pump design.	Same	Same
Indications for Use	Connects to designated syringe or infusion pump model used in hospital, ambulatory and home care environments.	Same	Same
Operating Principle	The patient presses on the button integral to the design of the cable and signals a request for medication to the syringe or infusion pump that processes this request in accordance with the parameters entered by the healthcare worker and the limitations established in the pump.	Same	Same
Operating Voltage	3.3 VDC to 5 VDC	Same	Same
Safety	Double insulation of conductors	Same	Same
Performance Features	Dose Units, Dose/Delivery Accuracy	Same	Same

Environmental Features	Operating Temperature, Storage Temperature, Relative Humidity, Pressure	Same	Same
Cable Length	6 feet nominal	Same	Same
BioMed Settings	No configuration settings available for customization on the PCA Button Cable. All the settings are entered in the mating syringe or infusion pump.	Same	Same

Performance, General Safety and Effectiveness

AIV's devices in this submittal are only the **Patient Pendant Bolus Cables** and are only intended as replacements for the OEM accessories for the syringe and infusion pump. Performance criteria are the indication of a patient request for medication event when the patient presses the button, and an absence of this event when the button is not activated. The accuracy of measurement is more a function of the patient syringe or infusion pump rather than the cable accessories. The AIV **Patient Pendant Bolus Cables** are limited by the indications for use of the connected syringe or infusion pump equipment.

The following non clinical test protocol was identified for each of the AIV **Patient Pendant Bolus Cables** models:

1. Verification Testing – Construction and operation consistent with the technical specifications.

2. Storage and Cleaning Tests – Subjecting the Cables to repeated cleaning cycles and to storage environmental limits and confirming that operation remains consistent with the technical specifications.

3. Performance Testing – A switch activation test pattern and pump test program were used to show that under identical activation patterns and pump programs, the number of dose requests is equivalent and the fluid dispensed is consistent with the accuracy of the target pump. A custom test system was constructed and validated to generate the patient activation patterns and conduct these tests.

Testing was performed by AIV at their facility in Harmans, MD. All test reports are in Section E.

Because of the extreme similarities of the AIV product to the OEM, the consequences of a modified device are the same for both AIV and OEM devices. Also, because of these extreme similarities, the consequences of a device failure are the same for both AIV and OEM devices.

A risk management file was developed and used throughout the development process – please see Section G.

Clinical Testing

No clinical testing was performed for these devices.

Conclusion

The non clinical testing has demonstrated that the AIV **Patient Pendant Bolus Cables** are as safe, as effective, and perform as well as the legally marketed accessories for syringe and infusion pumps.

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. Majdi F. Shomali
Vice President – Engineering
American IV Products, Inc.
7485 Shipley Avenue
Harmans, Maryland 21077

APR 12 2012

Re: K120209
Trade/Device Name: Patient Pendant Bolus Cable
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: March 26, 2012
Received: March 27, 2012

Dear Mr. Shomali:

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): K120209

Device Name: **Patient Pendant Bolus Cable**

Indications For Use:

This device is an accessory for a syringe or infusion pump. The healthcare worker connects the device to the corresponding pump. The patient uses the switch on the cable to signal the syringe pump to deliver medication consistent with the parameters entered into the pump by the healthcare worker.

AIV Part #	Corresponding Pump
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BC10969	Abbott / Hospira Lifecare 4100 PCA Plus II

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)

Waiting Cosign for RZC. 4/11/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120209