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ATTACHMENT 5

APR 12 2011

510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Carmel Pharma ab summary for the Infusion Adapter C100 included in:

PhaSeal® - A Closed System Drug Transfer Device for Preparation and Administration of Parenteral Drugs

SUBMITTER'S NAME:	Carmel Pharma AB
ADDRESS:	Aminogatan 30 SE-43153 Mölndal Sweden
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DATE OF SUBMISSION:	December 10, 2010

1. **Identification of device**

Proprietary Name:	PhaSeal Infusion Adapter
Common Name:	I.V. Fluid Transfer Set
Classification Status:	Class II per 21 CFR 880.5440
Product code:	LHI

2. **Equivalent devices**
Infusion Adapter C100 is previously cleared in K023747.

3. **Description of the Device**
The Injector is a sterile device for single-use within the PhaSeal® closed transfer device system for preparation and administration of parenteral drugs.

4. **Intended use.**
The intended use of this device is to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

5. Technological characteristics, comparison to predicate device.

Infusion Adapter

Subject	C100	C100 K023747	Equiv.
Indication for use	The indication for use is admixing of drug into an IV container and administration/transfer of drug from the container to an external IV line, while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the admixing, administration and disposal process.	The Infusion Adapter serves as the connecting part between the IV bag and an external IV line (e.g. IV regulators). The Infusion Adapter has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal double membrane technique	Yes
Intended use	The intended use of this device is to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.	The intended use of this device is to administer fluids from one a container to a patient's vascular system through a needle or catheter inserted to a vein. The infusion adapter mates with the PhaSeal injector bayonet fitting which prevents drug spillage into the environment	Yes
Flushing of system prior to use	No	Yes	
Material	Spike port: TPE Spike housing: PP Spike Cap: PP	Spike port: TPE Spike housing: ABS Spike Cap: PP	Yes
Fitting connection	Spike housing: to Injector and to infusion bag Spike port: to external spike included in an administration set	Spike housing: to Injector and to infusion bag Spike port: to external spike included in an administration set	Yes
Sterilization method	EtO	EtO	Yes

6. Summary of design control activities

Performance testing – general performance

Modification	Test Performed	Passed
Performance testing refer to verify integrity of th device and compatibility with the relevant other PhaSeal components.	Pulling force, torque test in connection to other PhaSeal components, liquid flow, air tightness, handling tests,	Yes

Material testing – specific requirements

Modification	Test Performed	Passed
Specific requirements refer to integrity of the material in combination with the aggressive chemicals.	Functional and mechanical properties on product after 24h and 72h of chemical exposure with Etopside, Taxo and Busulfani	Yes

Biocompatibility

Modification	Test Performed	Passed
The Infusion Adapter is indirect invasive, duration normally 1-2 hours, may be 24-48 hours if patient is hospitalised.	Systemic Injection test, Cytotoxicity, Hemolysis, Dermal sensitization, Intracutaneous test and Physicochemical tests – plastic.	Yes

7. Discussion of performance testing.

The tests performed show that that Infusion Adapter C100 fulfil the stated requirements and therefore comply with the claims of the intended use.

8. Conclusion

Based on comparison to the predicate device, we come to the conclusion that the Infusion Adapter C100 included in the PhaSeal System, is substantially equivalent to previously cleared predicate devices and presents no new concerns about safety and effectiveness.

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. Kjell Andreasson
Manager, Regulatory Affairs
Carmel Pharma AB
Aminogatan 30
Mölndal
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APR 12 2011

Re: K110023
Trade/Device Name: Infusion Adapter C100
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 1, 2011
Received: March 8, 2011

Dear Mr. Andreasson:

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,

for

Anthony 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

Attachment 1

Indications for Use Statement

510(k) Number (if known) K110023

Device Name Infusion Adapter C100

Indications for Use The indication for use is admixing of drug into an IV container and administration/transfer of drug from the container to an external IV line, while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the admixing, administration and disposal process.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: Yes (Per 21 CFR 801. 109) OR Over-The-Counter Use: No

4/8/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K110023