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ATTACHMENT 5

510(K) SUMMARY

MAR 2 3 2009

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Carmel Pharma ab summary for the Protector P14, P21, P28 and P50 included in:
PhaSeal® - A Closed System Drug Transfer Device for Preparation and Administration of Parenteral Drugs

SUBMITTER'S NAME:	Carmel Pharma ab
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CONTACT PERSON:	Kjell Andreasson
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DATE OF SUBMISSION:	February 20, 2009

1. Identification of device

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

2. Equivalent devices

Protector P14, P21 and P50 cleared in K001368

3. Description of the Device

The single lumen docking station of the Protector is fitted to the drug vial for the parenteral drug. The Injector is connected to the Protector and liquid transfer takes place through tightly fitting elastomeric double membranes to minimize leakage during reconstitution, administration and disposal processes. The Protector equilibrates the pressure difference which occurs when fluid or air is added to, or removed from the drug vial.

4. Intended use

Drug Vial Adapter for closed reconstitution of parenteral drugs.

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5. Technological characteristics, comparison to predicate device.

Comparison table

Protector 14

Subject	Modified P14	Predicate P14, K001368	Equivalent
Intended use	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Yes
Material	Polypropylene	Polypropylene	Yes
Spike	Stainless steel	Stainless steel	Yes
Drug vial size	∅ 13 mm	∅ 13 mm	Yes
Expansion chamber	20 ml	20 ml	Yes
Sterilization method	EtO	EtO	Yes

Protector 21

Subject	Modified P21	Predicate P21, K001368	Equivalent
Intended use	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Yes
Material	Polypropylene	Polypropylene	Yes
Spike	Stainless steel	Stainless steel	Yes
Drug vial size	∅ 20 mm	∅ 20 mm	Yes
Expansion chamber	20 ml	20 ml	Yes
Sterilization method	EtO	EtO	Yes

Protector 28

Subject	Modified P28	Predicate P50, K001368	Equivalent
Intended use	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Yes
Material	Polypropylene	Polypropylene	Yes
Spike	Plastic	Stainless steel	No
Drug vial size	∅ 28 mm	∅ 28 mm	Yes
Expansion chamber	50 ml	50 ml	Yes
Sterilization method	EtO	EtO	Yes

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Protector 50

Subject	Modified P50	Predicate P50, K001368	Equivalent
Intended use	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Drug Vial Adapter for closed reconstitusion of parenteral drugs.	Yes
Material	Polypropylene	Polypropylene	Yes
Spike	Stainless steel	Stainless steel	Yes
Drug vial size	∅ 20 mm	∅ 20 mm	Yes
Expansion chamber	50 ml	50 ml	Yes
Sterilization method	EtO	EtO	Yes

6. Discussion of performance testing.

The Protectors have been tested and found in compliance with applicable requirements and standards specifications.

7. Conclusion

Based on comparison to the predicate device, we come to the conclusion that the Protectors P14, P21, P28 and P50 included in the PhaSeal System, are 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
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Mr. Kjell Andreasson
President Quality Assurance and Regulatory Affairs
Carmel Pharma AB
Box 5352
SE 402 28 Goteborg
SWEDEN

Re: K090634
Trade/Device Name: Protector P14, P21, P28 and P50
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: February 20, 2009
Received: March 9, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting 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)

Device Name Protector P14, P21, P28 and P50

Indications for Use The indication for use is reconstitution and transfer of drug solutions from one container to another while minimizing exposure to potentially hazardous drugs aerosols and spills that can occur during the reconstitution, 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 OR Over-The-Counter Use: No
(Per 21 CFR 801. 109)

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

510(k) Number: K090834