

SUMMARY OF SAFETY AND EFFECTIVENESS DATA**Carmel Pharma AB**

MAR - 3 1998

**PhaSeal® closed system for the preparation
and administration of parenteral drugs****Carmel Pharma Contact Person**

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Device Name

PhaSeal® closed system for the preparation and administration of parenteral drugs.

Infusion Adapter
Protection Cap
Secondary Set
Extension Set

Predicate Devices

- Codan Medlon, IV Administration Set – Catalog Rev 3/1/93 B&P, preamendment device
- Carmel Pharma ab, PhaSeal, a closed system for parenteral drugs, K972527

Product Description, Function, Safety and Efficacy

PhaSeal is a closed system for preparation and administration of parenteral drugs where the component devices are dedicated to each other to create the system. These single use devices are designed to promote safe handling of medications, particularly cytotoxic drugs. Leakage of drug into the environment is effectively avoided during all three phases of drug handling when the PhaSeal system is used: the preparation of the drug, the administration of the drug to the patient, and waste handling.

All drug transferring utilizes a patented double membrane technique. Each component devices is sealed off with an elastomeric membrane cover. The membranes are joined together and transfer is made via a specially cut injection cannula. When the component devices of the system are separated after transfer, the membranes act as tight seals that prevent leakage.

- **PhaSeal Infusion Adapter - Intravascular Administration Set**
The **Infusion Adapter** serves as a the connecting part between the IV bag and an external IV line. (Example IV regulators.) The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique.

- **PhaSeal Protection Cap – Special accessories**
The **Protection Cap** is intended to be used as a mechanical cover for the membrane in the bayonet fitting of PhaSeal devices. The Protection Cap mates with the other PhaSeal components equipped with the bayonet fitting. One end of the Protection Cap has a male bayonet fitting and in the other a female bayonet fitting.
- **PhaSeal Secondary Set – Intravascular Administration Set**
The Secondary Set is a non-vented infusion set used when drug is handled as an admixture and is administered via Intravenous infusion. The Secondary Set has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal technique.
- **PhaSeal Extension Set - Intravascular Administration Set**
The Extension Set serves as the port for bolus injection with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The Extension Set has a built in Connector which makes it possible inject drugs into the IV line of the patient using the sealed double membrane technique.

Comparison of Predicate Devices/Equivalence

- **PhaSeal Infusion Adapter**
Is substantially equivalent to Codan Medlon Inc. Vented Set (C 302 and C430) and Carmel Pharma ab, Infusion Set in that they all use similar components and provide a pathway to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. (Neither device provides the needle or catheter.)
- **PhaSeal Protection Cap**
Is substantially equivalent the Codan Medlon Inc. (BC 103) Special Accessories Luer Lock Plug in both being a protection and mechanical cover for a connections to IV systems. Protection Cap is substantially equivalent with Carmel Pharma ab Connector in design, the bayonet fitting and material.
- **PhaSeal Secondary Set**
Is substantially equivalent to Codan Medlon Inc. Vented Set (C 302) and Carmel Pharma ab, Infusion Set in that they all use similar components and provide a pathway to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. (Neither device provides the needle or catheter.)
- **PhaSeal Extension Set**
Is substantially equivalent to Codan Medloc Inc. Vented Set (BC 589) and Carmel Pharma ab, Infusion Set in that they all use similar components and provide a pathway to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. (Neither device provides the needle or catheter.)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1998

Mr. Britt Novén
Manager, Regulatory Affairs
Carmel Pharma AB
Box 5352
S-402 28 Göteborg, Sweden

Re: K980381
Trade Name: PhaSeal® closed system for the preparation
and administration of parenteral drugs
Regulatory Class: II
Product Code: LHI
Dated: January 30, 1998
Received: February 2, 1998

Dear Mr. Novén:

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.

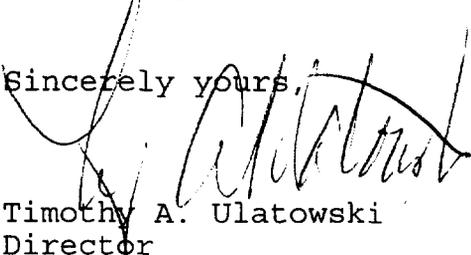
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 pre-market notification submission does

not affect any obligation you might have under sections 531 through 542 of 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) 594-4618. 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,



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

Enclosure

27. Indications for Use Statement:

510(k) Number (if known): _____

Device Name: PhaSeal® closed system for the preparation and administration of parenteral drugs

Indications for Use:

PhaSeal Infusion Adapter - Intravascular Administration Set

The **Infusion Adapter** serves as the connecting part between the IV bag and an external IV line. (Example IV regulators.) The **Infusion Adapter** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed double membrane technique.

PhaSeal Protection Cap – Special accessories

The **Protection Cap** is intended to be used as a mechanical cover for the membrane in the bayonet fitting of PhaSeal devices. The **Protection Cap** mates with the other PhaSeal components equipped with the bayonet fitting. One end of the **Protection Cap** has a male bayonet fitting and in the other a female bayonet fitting.

PhaSeal Secondary Set – Intravascular Administration Set

The **Secondary Set** is a non-vented infusion set used when drug is handled as an admixture and is administered via Intravenous infusion. The **Secondary Set** has a built in Connector which makes it possible to admix drugs into the infusion solution using the sealed PhaSeal technique.

PhaSeal Extension Set - Intravascular Administration Set

The **Extension Set** serves as the port for bolus injection with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The **Extension Set** has a built in Connector which makes it possible inject drugs into the IV line of the patient using the sealed double membrane technique.

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

Concurrence of CDRH, Office of Device Evaluation

Patricia Oscenti

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

510(k) Number 1980381

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use _____