APP VI
K972527
Sept. 18, 1997

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Carmel Pharma AB
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.

Protector 20
Injector Luer
Connector Luer Lock
Infusion Set

Predicate Devices

- Bristol-Myres Squibb/Mead Johnson Oncology Products (Survival Technology), CytoGuard® Drug Reconstitution Device, K883614
- Becton Dickinson, SafetyGlide™ Shielding IM Injection Needle, K951254
- Sherwod Davis & Geck, Monoject® Luer Adapter, K940961
- Codan Medlon, IV Administration Set – Catalog #443, preammendment device

Product Description, Function, Safety and Efficacy

The PhaSeal™ closed system for preparation and administration of parenteral drugs has four component devices that 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 element 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 elements of the system are separated after transfer, the membranes act as tight seals that prevent leakage.

PhaSeal utilizes a built-in, patented pressure equalization technique. Air passes from the vial into a special expansion chamber. Neither excess pressure nor vacuum can occur during drug preparation. This effectively prevents aerosol leakage.

- **PhaSeal Protector 20** - Drug Vial Transfer Adapter
  The Protector 20 is fitted to the drug vial and is used as a docking station between the drug vial for the parenteral drug and Injector Luer. In addition the Protector 20 equilibrates the pressure

difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that can occur during the reconstitution, administration and disposal processes.

- **PhaSeal Injector Luer** – Drug Transfer Needle Device
  The Injector Luer has an encapsulated cannula that is permanently locked onto a syringe using a Luer fitting. Sealed transfer of diluent, drug or air, between the single-use syringe and the various components in the system can be made via the Injector Luer in both the preparation and administration phases.

- **PhaSeal Connector Luer-Lock** – Luer Lock Device
  The Connector Luer Lock ensures a sealed connection between the single-use syringe and Injector Luer and the patient's IV line. With the help of the Connector Luer Lock, injections can be made without drug spillage.

- **PhaSeal Infusion Set** - Intravascular Administration Set
  The Infusion Set is a non-vented infusion device that has a built-in connector to be used as a way of making additions of parenteral drugs to infusion fluids in a closed system. The Infusion Set may be used to administer the infusion fluid.

Comparison of Predicate Devices/Equivalence

- **PhaSeal Protector 20**
  Is substantially equivalent to the CytoGuard Drug Reconstitution Device in that they both serve as a docking station for drug vials and act to minimize or eliminate the aerolization of drug being transferred from the drug vial into a single-use syringe.

- **PhaSeal Injector Luer**
  Is substantially equivalent to the Becton Dickinson SafetyGlide Shielding IM Injection Needle in that they both transfer fluid and drug between drug vials and infusate. In addition they both have protected needles which provide protection from accidental needle sticks.

- **PhaSeal Connector Luer Lock**
  Is substantially equivalent to the Sherwod Davis & Geck, Monoject® Luer Adapter in that they both provide a means of connecting various components of a drug delivery system via a luer fitting.

- **PhaSeal Infusion Set**
  Is substantially equivalent to the Codan Medlon, IV Administration Set – Catalog #443 in that they both 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.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Fred Schlador
Consultant
Quality System Consulting
C/O Carmel Pharma AB
1425 Cressa Court
Carlsbad, California 92009

SEP 18 1997

Re: K972527
Trade Name: PhaSeal™ System For Sealed Handling Of Chemotherapeutic AG
Regulatory Class: II
Product Code: LHI
Dated: June 30, 1997
Received: July 7, 1997

Dear Mr. Schlador:

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 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 premarket 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): K972527

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

Indications for Use:

PhaSeal Protector 20 - Drug Vial Transfer Adapter
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Patricia Cascente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972527

Prescription Use ____ OR Over the Counter Use ✓
(Per 21 CFR 801.109)