K060866

Exhibit 8

APR 2 8 2006

Special 510(k)
Summary

Company name: **Carmel Pharma AB**

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

Device name: **Y-site Line**

PhaSeal is a closed system for handling 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 double membrane technique. Each component device is sealed off with an elastomeric membrane. 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, Y-site Line

The **Y-site Line** serves as the port for IV administration with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The **Y-site Line** has a built in Connector which makes it possible administer drugs into the IV line of the patient using the PhaSeal Injector. Liquid transfer takes place through tightly fitting elastomeric membranes to minimize exposure to potentially hazardous drug aerosols and spills that occur during the administration and disposal processes.

Comparison of Predicate Devices/Equivalence

The device is substantially equivalent to previously cleared PhaSeal devices included in 510(k) Number K980381.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Mr. Kjell Andreasson
Vice President Quality Assurance and Regulatory Affairs
Carmel Pharma AB
Aminogatan 30, Molndal, Box 5352
Goteborg, Sweden SE 402 28

Re: K060866
Trade/Device Name: **PhaSeal Y-Site Line**-Intravascular Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: March 27, 2006
Received: March 30, 2006

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.

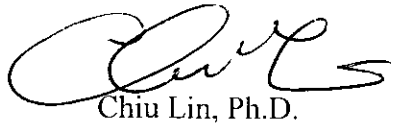
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K060866

Device name: **PhaSeal Y-site Line** – Intravascular Administration Set

Indications for use:
The Y-site Line serves as the port for IV administration with PhaSeal if there is no Luer Lock fitting, for Connector Luer Lock in the patients IV line. The Y-site Line has a built in Connector which makes it possible to administer drugs into the IV line of the patient using the sealed double membrane technique.

Prescription Use: Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use: No (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)

Anthony D. [illegible]

[illegible]logy, General Hospital,
[illegible] Devices

K060866