November 3, 2021

Pharmacia, Inc.
Albert Mayo
800 Centennial Ave.
Piscataway, New Jersey 08854-3911

Re: K864524
Trade/Device Name: Sperm Select(tm)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL

Dear Albert Mayo:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 2, 1987. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code MQL.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Monica Garcia, OHT3: Office of Gastro-Renal, Ob-Gyn, General Hospital and Urology Devices, (240) 402-2791, Monica.Garcia@fda.hhs.gov.

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastro-Renal, Ob-Gyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 2 1987

Mr. Albert P. Mayo
Manager
Regulatory Affairs
Pharmacia, Inc.
800 Centennial Avenue
Piscataway, New Jersey 08854

Re: K864524
Sperm-Select™

Dated: November 6, 1986
Received: November 17, 1986

Dear Mr. Mayo:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Jerome A. Donlon M.D. Ph.D.

Jerome A. Donlon, M.D., Ph.D.
Director, Division of Clinical Laboratory Devices
Center for Devices and Radiological Health