K980077

APR - 2 1998

APPENDIX A - 510(k) Summary

A. Identification Information

1) **Submitter's Information:**

a) **Submitter's Name and Address:**

Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, OH 45244

b) **Phone Number:** 1-800-543-1980

c) **Contact Person:** Allen D. Nickol, Ph.D.
Director of Scientific and Regulatory Affairs

d) **Date Summary Prepared:** December 24, 1997

2) **Name of Device: Para-Pak SPINCON.**

Classification Name: Device, Parasite Concentration 83LKS

3) **Predicate Equivalent Device:** Para-Pak CON-Trate

4) **Description of Device:** Para-Pak SPINCON involves passing a surfactant treated, preserved stool specimen through a preliminary screen by gravity flow. The surfactant helps to break down fecal aggregates, thus freeing parasites. The specimen is then forced by centrifugation through a series of two screens with successively smaller mesh. The series of screens, not present in other devices, trap stool debris, yet allow even the larger parasites to pass through. This second filtration step eliminates the need for organic solvent extraction of the stool specimen. The resulting pellet may be examined for the presence of parasites by standard wet mount procedures.

SPINCON Devices: 200/500
SPINCON Caps: 200/500
SPINCON Preliminary Funnel Screens: 200/500
Para-Pak Surfactant: 33ml

5) **Intended Use:** Para-Pak SPINCON is a unique, patent pending system for the concentration of eggs, larvae, and protozoa from preserved fecal specimens. Specimens preserved in 10% Formalin, Sodium Acetate Formalin (SAF), and ECOFIX may be used with the system.

6) **Comparison with Predicate Device:** The following comparison of the use, technology, function and performance supports the Statement of Equivalence with the predicate device.

Method	Para-Pak® SPINCON	Para-Pak® CON-Trate
Intended Use	System for concentrating and recovering helminth eggs, larvae, and protozoan cysts from feces	
Results	Final pellet consists of concentrated parasites	
Technology	Utilizes filtration and centrifugation	
Function	Treat stool with surfactant. Filter through primary funnel with mesh screen. Add saline. Centrifuge through series of smaller mesh screens. Remove supernatant. Resuspend in fixative. Prepare wet mount.	Treat stool with surfactant. Filter through primary Funnel with mesh screen. Add saline. Centrifuge. Remove supernatant. Resuspend in buffered formalin and ethyl acetate. Centrifuge. Remove supernatant. Prepare wet mount.
Final Pellet	Useable for saline or iodine wet mount microscopic evaluation	
Performance	Clinical studies demonstrate equivalent performance and recovery	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Allen D. Nickol, Ph.D.
Director of Scientific and Regulatory Affairs
Meridian Diagnostics, Inc.
3471 River Hills Drive
Cincinnati, Ohio 45244

APR - 2 1998

Re: K980077
Trade Name: Para-Pak® SPINCON
Regulatory Class: I
Product Code: LKS
Dated: June 30, 1997
Received: March 25, 1998

Dear Dr. Nickol:

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 requirements, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

C. **Indications for Use Statement:**

510(k) Number (if known): ~~NA~~ K980077

Device Name: Para-Pak® SPINCON

Indications For Use: Para-Pak SPINCON is for the concentration of eggs, larvae, and protozoa from preserved fecal specimens. Specimens preserved in 10% Formalin, Sodium Acetate Formalin (SAF), and ECOFIX may be used with the system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980077

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)