



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

RFD-94-01

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7
301-443-1306

Food and Drug Administration
Rockville MD 20857

March 28, 1994

Martin J. Lee, Ph.D.
Laboratory Director
Great Smokies Diagnostic Laboratory
18A Regent Park Boulevard
Asheville, North Carolina 28806

Re: Request For Designation
Intestinal Permeability Test System
Our File: RFD-94-01

Dear Dr. Lee:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on January 26, 1994.

The Intestinal Permeability Test System is a product that consists of a drink, [] The drink contains five grams of lactulose, one gram of mannitol, ten grams of glycerine and water. The Intestinal Permeability Test System is intended to measure lactulose and mannitol in urine. Measurements obtained by the test are intended for use in the diagnosis [] [] of gastrointestinal malabsorption syndrome. Great Smokies recommends that the Center for Devices and Radiological Health (CDRH) be assigned jurisdiction for the premarket review and regulation of the product.

After considering the information provided in the above-referenced request and consulting with officials in the Center for Drug Evaluation and Research (CDER) and CDRH, I am in substantial agreement with Great Smokies' recommended disposition of this product. Therefore, I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of the Intestinal Permeability Test System. The product will be regulated under the device provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c et seq. CDRH will consult with CDER, as appropriate.

Please submit a copy of this letter in your initial submission to CDRH. The Division of Clinical Laboratory Devices in CDRH will be the primary reviewing division. For further information, please

contact Ms. Cornelia Rooks, Chief, Clinical Chemistry Branch, 1390 Piccard Drive, Room 150 (HFZ-440), Rockville, MD 20850, 301-594-1243.

If you have any other questions concerning this matter, please do not hesitate to telephone the Deputy, Mr. Stephen Unger, at 301-443-1306.

Sincerely yours,



Amanda B. Pedersen
Chief Mediator and Ombudsman

cc: Ms. Cornelia Rooks