

K 991156

MAY 28 1999

- H. 510(k) Summary Date prepared: March 30, 1999
1. **Submitter:** Great Smokies Diagnostic Laboratory
63 Zillicoa Street
Asheville, NC 28801
(800) 522-4762
- Contact:** Dr. Stephen Barrie
2. **Classification Name:** Xylose Test System (21 CFR 862.1820)
- Common Usual Name:** Intestinal Permeability Test System;
Lactulose/Mannitol Test
- Proprietary Name:** Great Smokies Diagnostic Laboratory
Intestinal Permeability Test System
3. **Statement of Equivalence**
Great Smokies lactulose/mannitol intestinal permeability test is substantially equivalent to preamendments devices classified under 21 CFR 862.1820, Xylose Test System, Class I (exempt from 510(k) as of February 2, 1998). Great Smokies intestinal permeability test system has the same intended use and similar technology and performance characteristics. In addition, mannitol and xylose are essentially the same compound and lactulose is insignificantly different from xylose. Like lactulose/mannitol test systems, xylose test systems are used to measure xylose (a sugar) in urine. The measurement is used in the diagnosis of gastrointestinal malabsorption syndrome.
4. **Device Description**
The device is a kit consisting of exempt components and accessories (urine specimen transport tubes (one white-capped "before drink" specimen tube and one purple-capped "after drink" specimen tube), a pipette, a small urine collection cup, a large urine collection container, a biohazard bag with absorbent pad, and a drink accessory (5g lactulose, 1g mannitol, 10g glycerine, and 3.84 ml water)). The drink is ingested after an overnight fast, and voided urine is then collected over a period of 6 hours to measure the level of lactulose and level of mannitol in urine and to obtain a ratio; the result is expressed as the percent recovery of an ingested dose of lactulose divided by the percent recovery of an ingested dose of mannitol. The measurement is used in the diagnosis of gastrointestinal malabsorption syndrome (a group of disorders in which there is abnormal absorption of dietary constituents, e.g., excessive absorption of substances or excessive loss from the body of nonabsorbed substances).

5. **Indications For Use**

The Great Smokies lactulose/mannitol test for intestinal permeability is intended to measure the ratio of lactulose to mannitol in urine; the measurement is used in the diagnosis of gastrointestinal malabsorption syndrome.

6. **Technological Characteristics**

The technological characteristics of the device do not vary from those in the claimed predicate, except that mannitol is substituted for xylose and lactulose is added as an internal control.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 28 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dr. Stephen Barrie
Official Correspondent
Great Smokies Diagnostic Laboratory
63 Zillicoa Street
Asheville, NC 28801

Re: K991156
Trade Name: Great Smokies Diagnostic Laboratory
Intestinal Permeability Test System
Regulatory Class: I
Product Code: JOC
Dated: March 30, 1999
Received: April 07, 1999

Dear Dr. Barrie:

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 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). 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.

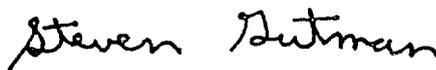
Page 2

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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

K991156

B. Indications for Use

The Great Smokies lactulose/mannitol test for intestinal permeability is intended to measure the ratio of lactulose to mannitol in urine; the measurement is used in the diagnosis of gastrointestinal malabsorption syndrome.

Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K991156

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over the Counter Use