



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 10, 2013

Micro Direct, Inc.
c/o Mr. David R. Staszak
840 Pownal Road
P. O. Box 239
Auburn, Maine 04212-0239

Re: k963376
Trade/Device Name: MicroH²
Regulation Number: 21 CFR 862.1820
Regulation Name: Xylose test system
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9 (c) (9)
Product Code: NRH
Dated: November 19, 1996
Received: November 21, 1996

Dear Mr. Staszak:

This letter corrects our substantially equivalent letter of January 24, 1997.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

510(k) Number (if known):

Device Name: *Micro H₂*

Indications for Use:

The *Micro H₂* is a hand held hydrogen monitor, used in the screening and diagnosis of lactose malabsorption, a condition that produces increased hydrogen levels in the blood when unabsorbed lactose reacts with bacteria in the intestines. This increased level of hydrogen is expired and can be measured after ingestion of lactose following a period of fasting.

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Target Population: Adult, Child and Infant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Cheryl Forman
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K91e3376

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

37