DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 1999

Mr. Andy Hollingsworth
Regulatory Affairs Manager
Oxoid Limited
Wade Road Basingstoke
Hants RG24 8PW
ENGLAND

Re: K982634
Trade Name: DRYSPOT® Infectious Mononucleosis Kit
Regulatory Class: II
Product Code: KTN
Dated: December 21, 1998
Received: December 28, 1998

Dear Mr. Hollingsworth:

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.

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,

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

510(K) Submission for Oxoid

Dryspot Infectious Mononucleosis Kit

510(K) Number: K982634

Device Name: Dryspot Infectious Mononucleosis Kit

Indications for Use:

Acute infectious mononucleoisis is a self-limiting clinical syndrome that most commonly occurs in teenagers and young adults in developed nations. In developing, IM can occur much earlier in life. This assay is intended for use as an aid in the rapid diagnosis of IM.

The Dryspot IM Test is a simple two minute latex agglutination test for the detection of the specific heterophile antibody associated with IM in serum and plasma. The purified specific heterophile antigen from bovine red cell membranes is used to coat latex particles. When a drop of serum or plasma containing the heterophile antibody associated with IM is mixed with a drop of latex, visible agglutination of the latex occurs within 2 minutes. Agglutination will not occur when such an antibody is absent.

A final diagnosis of IM, however, should only be made when clinical and haematological findings as well as the results from the Dryspot IM Test have been taken into consideration.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982634

Prescription Use.....✓..... OR Over-the-Counter-Use.....