K973454

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SUMMARY OF SAFETY AND EFFECTIVENESS

The proposed changes to the intended use of IMAGEN™ Respiratory Screen outlined in this supplementary information have no effect on the safety and effectiveness of the IMAGEN™ Respiratory Screen product, as outlined in the original submission.

Performance characteristics for the additional intended uses have been established by external clinical evaluation against the Bartels Viral Respiratory Screening and Identification Kit and standard viral isolation reference methods used for screening for the presence of respiratory viruses. (Exhibit E)

IMAGEN™ Respiratory Screen is intended for use in laboratories where qualified technicians are familiar with routine indirect immunofluorescence testing for microbiological diagnosis. However specific quality control information regarding the validity of test results is included in the Product Insert, to facilitate reliable and reproducible results and minimise the occurrence of false positive or false negative results. Procedures include the use of positive and negative control slides, a negative control reagent and specifications for acceptable results. Technical references and a Customer Services phone number are provided to aid the user in further trouble-shooting.

IMAGEN™ Respiratory Screen is similar in use and technology to Bartel's Viral Respiratory Screening and Identification Kit, which is already in commercial distribution in the U.S.

Further information regarding the safety and effectiveness of IMAGEN™ Respiratory Screen will be made available within 30 days of request by any person. This information excludes confidential patient information and proprietary manufacturing procedures pertinent to this device. Please contact:

Dr Elisabeth Silver,
Regulatory Affairs Manager,
DAKO Limited,
Denmark House,
Angel Drove, Ely,
Cambridgeshire, CB7 4ET, UK.

Phone (353) 669911
Fax (353) 668989

Signature: Elisabeth Silver Date: 17th September 1997

E.A SILVER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Elisabeth A. Silver, Ph.D.
Regulatory Affairs Manager
DAKO Diagnostics Ltd.
Denmark House
Angel Drove, Ely
Cambridgeshire CB7 4ET
England,
United Kingdom

DEC 22 1997

Re: K973954
Trade Name: IMAGEN™ Respiratory Screen
Regulatory Class: I
Product Code: GNW
Dated: September 22, 1997
Received: October 9, 1997

Dear Dr. Silver:

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

ITEM 5

INDICATIONS FOR USE STATEMENT

510(k) Number: **Supplement to K962037**

Device Name: **IMAGEN™ RESPIRATORY SCREEN**

Indications for Use: **The IMAGEN™ Respiratory Screen is a qualitative indirect immunofluorescence screening test for the presumptive detection of respiratory viruses; Respiratory Syncytial Virus (RSV), Influenza A and B, Parainfluenza types 1, 2 and 3 and Adenovirus in respiratory specimens (nasopharyngeal aspirates) and in cell cultures.**

Signature: Elisabeth Silver

Date: 17th September 1997

E A SILVER, Ph.D.
Regulatory Affairs Manager

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

John Tiebhurst 12/19/97
John Tiebhurst MT
Interim Chief, Microbiology Branch

Prescription Use ✓ or Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)