

K981226



SEP 28 1998

ITEM 3

510(k) SUMMARY

Submitter's Name: DAKO Limited  
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Contact Name: Dr. Ron Newstead, Quality Manager

Date of preparation: 17th September 1998

Trade Name(s): IMAGEN™ Parainfluenza Virus Group (Types 1, 2 and 3)  
- Product Code (K6103)

IMAGEN™ Parainfluenza Virus Types 1, 2 and 3  
- Product Code (K6104).

IMAGEN™ Parainfluenza Virus Group (Types 1, 2 and 3) is for the detection and confirmation of the presence of Parainfluenza virus antigens in cell culture preparations and direct specimens (nasopharyngeal aspirates) from paediatric populations. A single reagent is provided which contains a mix of purified murine monoclonal antibodies specific to Parainfluenza virus types 1, 2 and 3, conjugated to fluorescein isothiocyanate (FITC).

IMAGEN™ Parainfluenza Virus Types 1, 2 and 3 is for the detection and differentiation of Parainfluenza virus type 1, 2 and 3 antigens respectively in cell culture preparations and direct specimens (nasopharyngeal aspirates) from paediatric populations. Three individual reagents are provided which each contain a purified murine monoclonal antibody specific to either Parainfluenza virus type 1, 2 or 3, conjugated to fluorescein isothiocyanate (FITC).

The clinical performance of The IMAGEN™ Parainfluenza Virus Group (Types 1, 2 and 3) and IMAGEN™ Parainfluenza Virus Types 1, 2 and 3 was compared with that achieved with the Parainfluenza typing reagents within the Bartels Viral Respiratory Screening and Identification kit (Predicate Device).

The technological characteristics of the IMAGEN™ Parainfluenza Virus Group (Types 1, 2 and 3) and IMAGEN™ Parainfluenza Virus Types 1, 2 and 3 differ from those of the Predicate Device in that they consist of directly FITC labelled type specific mouse monoclonal antibodies which are used in a one step direct immunofluorescence technique. The Predicate Device consists of individual type-specific mouse monoclonal antibodies which are used in a

two-step indirect immunofluorescence assay with a separate secondary conjugate specific for mouse monoclonal antibodies and conjugated to FITC.

The clinical performance characteristics of the IMAGEN™ Parainfluenza virus Group (Types 1,2 and 3) and the IMAGEN™ Parainfluenza virus Types 1, 2 and 3 tests were assessed in 3 routine diagnostic laboratories (1 in the US and 2 in the UK). Their performance was compared with the above named Predicate Device, and viral isolation.

The IMAGEN™ Parainfluenza virus Group (Types 1, 2 and 3) test was assessed on a total of 184 direct specimens at the US trial centre and showed a correlation of 98.4% (125/127) against the Predicate Device and 97.6% (164/168) against viral isolation. The relative sensitivity and specificity of the IMAGEN™ Parainfluenza virus Group (Types 1,2 and 3) test was 96.2% (25/26) and 99.0% (100/101) respectively against the Predicate Device and 97.9% (47/48) and 97.5% (117/120) respectively against viral isolation.

The IMAGEN™ Parainfluenza virus Types 1, 2 and 3 test was assessed on the same 184 direct specimens. Both the IMAGEN™ Parainfluenza virus Type 1 and Type 2 reagents showed a correlation, sensitivity and specificity of 100% against the Predicate Device. The IMAGEN™ Parainfluenza virus Type 3 reagent gave a correlation of 98.4% (125/127), sensitivity of 75% (3/4) and specificity of 99.1% (122/123) against the Predicate Device.

When compared with viral isolation both the IMAGEN™ Parainfluenza virus Type 1 and Type 2 reagents gave 100 % correlation, sensitivity and specificity. The IMAGEN™ Parainfluenza virus Type 3 reagent gave a correlation of 97.6% (164/168), sensitivity of 91.6% (22/24) and specificity of 98.6% (142/144).

The conclusions drawn from these clinical tests are that the comparison of the results obtained with the IMAGEN™ Parainfluenza virus Group (Types 1, 2 and 3) and IMAGEN™ Parainfluenza virus Types 1, 2 and 3 tests and the Predicate Device demonstrate that the IMAGEN™ Tests will provide an accurate means of detecting Parainfluenza virus antigens in respiratory specimens.



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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ron Newstead  
Quality Manager  
Dako Diagnostics Ltd.  
Denmark House, Angel Drove  
Ely  
Cambridgeshire  
United Kingdom

Re: K981226  
Trade Name: Imagen™ Parainfluenza Virus Group (Types 1, 2 and 3) and  
Imagen™ Parainfluenza Virus Types 1, 2 and 3  
Regulatory Class: I  
Product Code: GQP  
Dated: July 20, 1998  
Received: July 23, 1998

Dear Mr. Newstead:

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.

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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 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

Page 1 of 1

510(k) Number: K981266 (Supplement to K962037)

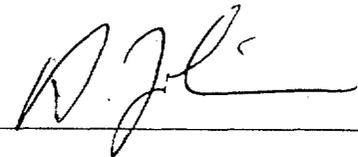
Devices Name: IMAGEN™ PARAINFLUENZA VIRUS GROUP (TYPES 1, 2 AND 3)  
IMAGEN™ PARAINFLUENZA VIRUS TYPES 1, 2 AND 3

Indications for Use: The IMAGEN™ Parainfluenza virus Group (Types 1, 2 and 3) is a qualitative direct immunofluorescence test for the presumptive detection and confirmation of parainfluenza virus type 1, 2 and 3 *antigens* in respiratory specimens (nasopharyngeal aspirates) from paediatric populations and in cell culture preparations.

The IMAGEN™ Parainfluenza virus Types 1, 2 and 3 is a qualitative direct immunofluorescence test for the presumptive detection and differentiation of parainfluenza virus type 1, 2 and 3 *antigens* respectively in respiratory specimens (nasopharyngeal aspirates) from paediatric populations and in cell culture preparations.

*A negative result obtained following direct staining of nasopharyngeal aspirates should be considered presumptive until confirmed by culture.*

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

18 September 1998

**Axel Johannsson**  
**Managing Director**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois  
(Division Sign Off)

Division of Clinical Laboratory Devices

510(k) Number K981266

PRESCRIPTION USE X