

510(k) SUMMARY

DIAGNOSTIC HYBRIDS, INC. D<sup>3</sup> HERPES SIMPLEX VIRUS IDENTIFICATION AND TYPING KIT

**Applicant** DIAGNOSTIC HYBRIDS, INC.  
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OCT 24 2007

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**Date of preparation of 510(k) summary:** September 27, 2007

**Device Name** Trade name – DIAGNOSTIC HYBRIDS, INC. D<sup>3</sup> HERPES SIMPLEX VIRUS IDENTIFICATION KIT  
Common name – Fluorescent antibody test for ID and typing HSV-1 and HSV-2  
Classification name – ANTISERA, FLUORESCENT, HERPESVIRUS HOMINIS 1,2 (21 CFR 866.3305, product code GQL)

**Legally marketed devices to which equivalence is claimed:**  
K880157 MicroTrak<sup>®</sup> HSV 1/HSV 2 Culture Identification and Typing Test  
K904167 Pathodx<sup>®</sup> Herpes Typing Kit

**Device Description** The Diagnostic Hybrids, Inc. D<sup>3</sup> DFA Herpes Simplex Virus Identification and Typing Kit uses two separate blends of HSV Type-1 (HSV-1) and HSV Type-2 (HSV-2) antigen-specific murine MAbs that are directly labeled with fluorescein for the rapid detection and typing of HSV. The reagents can specifically detect and type either HSV-1 or HSV-2. The HSV-1 MAbs were developed using HSV-1(f) cell lysate as immunogen – one MAb has been determined to be directed against HSV-1 glycoprotein C1; the antigen to the other is undetermined. The HSV-2 MAbs were developed using a HSV-2 recombinant glycoprotein G as immunogen.

**Kit Components:**

- HSV-1 DFA Reagent – One dropper bottle containing a blend of two fluorescein labeled murine monoclonal antibodies directed against HSV-1 specific glycoproteins. The HSV-1 MAbs were developed using HSV-1(f) cell lysate as immunogen – one MAb has been determined to be directed against HSV-1 glycoprotein C1, the antigen to the other is undetermined. The buffered, stabilized, aqueous solution contains Evan's Blue as a counter-stain and 0.1% sodium azide as preservative.
- HSV-2 DFA Reagent – One dropper bottle containing a blend of two fluorescein labeled murine monoclonal antibodies directed against HSV-2 specific glycoproteins. The HSV-2 MAbs were developed using a HSV-2 recombinant glycoprotein G immunogen. The buffered, stabilized, aqueous solution contains Evan's Blue as a counter-stain and 0.1% sodium azide as preservative

Section 5-1 of 5-5

- HSV-1/HSV-2 Antigen Control Slides - Individually packaged control slides containing wells with cell culture derived positive and negative control cells. Each slide consists of four wells containing acetone fixed cells; two wells of noninfected cells and one well each of HSV-1 infected cells and HSV-2 infected cells. Each slide is intended to be stained only one time.
  - PBS Concentrate - A 40X concentrate consisting of 4% sodium azide in phosphate buffered saline (after dilution to 1X in water, the concentration of sodium azide in the solution is 0.1%).
  - Mounting Fluid - an aqueous, buffered, stabilized solution of glycerol and 0.1% sodium azide.

The cells to be tested, on a slide prepared from a tube culture or on a monolayer of cells cultured in a multi-well plate or a coverslip in a shell vial, are fixed in acetone. The HSV-1 DFA Reagent or HSV-2 DFA Reagent is added to the cells to detect the presence of HSV specific viral antigens. After incubating for 15 to 30 minutes at 35° to 37°C, the stained cells are washed with the supplied Phosphate Buffered Saline (PBS). To prepare the slide for examination, a drop of the supplied Mounting Medium is added to the stained cells and a coverslip is placed on the slide. To prepare the centrifuge enhanced cell cultures for examination, a drop of Mounting Fluid is placed on a clean microscope slide. The coverslip is removed from the shell vial and placed on to the Mounting Fluid.

For multi-well plates, monolayers are fixed with an 80% aqueous acetone solution. The HSV DFA Reagent is added to the cells to detect the presence of any HSV specific viral antigens. After incubating for 15 to 30 minutes at 35° to 37°C, the stained cells are washed with the supplied Phosphate Buffered Saline (PBS). Mounting Fluid is added to each well to cover the monolayers.

The slides or wells are examined using a fluorescence microscope equipped with the correct filter combination for FITC at a magnification of 100-400X. Virus infected cells will be stained with bright apple-green fluorescence while uninfected cells will contain no apple-green fluorescence but will fluoresce red by the Evan's Blue counter-stain<sup>1</sup> which is included in the HSV DFA Reagent.

If no fluorescent cells are found, report result as, "No herpes simplex virus detected."

If fluorescent cells are found in the HSV-1 DFA Reagent stained monolayer, report result as "Herpes simplex virus type 1 isolated by cell culture". If fluorescent cells are found in the HSV-2 DFA Reagent stained monolayer, report result as "Herpes simplex virus type 2 isolated by cell culture." If fluorescent cells are found in both the HSV-1 and HSV-2 stained wells, the results should be reported as "Herpes simplex virus types 1 and 2 isolated by cell culture".

Included in the kit are HSV-1/HSV-2 Antigen Control Slides. A Control Slide is intended to function as an indicator that the kit reagents are working properly in the test. [The slides are prepared with wells of HSV-1 infected cells, HSV-2 infected cells, and uninfected cells.] Positive and negative controls must demonstrate appropriate staining characteristics for specimen results to be valid. Controls may also aid in the interpretation of test results.

It is recommended that cell culture positive (infected with known HSV isolate) and negative (uninfected cells) controls be run with each assay to provide a means to ensure adequate performance of the cell culture system used. If control cultures fail to perform correctly, results are considered invalid.

**Intended Use**

The Diagnostic Hybrids, Inc. D<sup>3</sup> DFA Herpes Simplex Virus Identification and Typing Kit is intended for use in the qualitative detection and typing of human herpes simplex virus type 1 and type 2 (HSV-1 and HSV-2) in cell cultures by immunofluorescence using fluoresceinated monoclonal antibodies (MAbs). Negative results do not rule out an infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Performance using direct specimen testing has not been evaluated.

**Explanation**

HSV infections in humans can cause lesions at a variety of sites, e.g., oral-facial,

genital, eye, and cutaneous sites.

When an appropriately sensitive cell line is infected with HSV, a characteristic deterioration of cells, termed cytopathic effect (CPE), can be observed. Tube culture, a classic format for virus amplification, can take several days before CPE is evident. In the case of those specimens with low titers of virus, 7 days of culture may be required by the standard tube culture method before CPE can be observed<sup>2,3,4,5,6</sup>.

The rate of isolation may be enhanced and the time required for HSV identification and typing may be decreased by centrifugation of specimens in shell vials or multi-well plates containing appropriately sensitive cell lines (centrifuge enhanced technique)<sup>7,8,9</sup>.

Even so, CPE may be difficult to interpret due to, for instance, deterioration of cells, which can result from toxic components present in the clinical specimen making microscopic examination of the infected cells problematic. Further, determination of type cannot be done with CPE alone. Because of this, immunofluorescence confirmation of cell culture is regarded as the standard for confirmation of a HSV positive result.

**Technological  
Characteristics**

Fundamental technology and intended use of the device are the same as those of the predicate devices, which are based on a standard immunofluorescence assay technique using cells inoculated with patient specimens. They employ directly labeled fluorescein monoclonal antibodies specific for HSV-1 and HSV-2 antigens enabling visualization of the infected cells. A summary is provided in the table below:

HSV Systems	DFA	Direct Specimens	Culture Confirmation	FITC Label	Monoclonal Antibody	Distinguishes HSV-1 and HSV-2
Diagnostic Hybrids, Inc.	Yes	No	Yes	Yes	Yes	Yes
MicroTrak <sup>®</sup> (Trinity)	Yes	No	Yes	Yes	Yes	Yes
PathoDx <sup>®</sup> (Remel)	Yes	Yes	Yes	Yes	Yes	Yes

**Non-clinical Performance**

Staining patterns of the conjugated monoclonal antibodies on HSV-1 and HSV-2 infected cells were similar to those of the predicate devices. Analytical specificity was evaluated by staining cultures infected with a number of ATCC reference HSV-1 and HSV-2 strains and found to react with all of them. The HSV-1 DFA Reagent and HSV-2 DFA Reagent were tested for cross-reactivity against a wide variety of other microorganisms and cells. No cross-reactivity was observed for 59 virus strains (cultured and processed for staining) or for 17 host culture cell types. Twenty-seven (27) bacterial cultures, one yeast and one protozoan culture were stained and examined for cross-reactivity, including *Staphylococcus aureus*, a protein-A-producing bacterium. Staining of *S. aureus* appeared as small points of fluorescence while all other cultures were negative. [Protein A will specifically bind to the Fc portions of conjugated antibodies. Such binding can be distinguished from viral antigen binding on the basis of morphology, i.e., *S. aureus*-bound fluorescence appears as small (~1 micron diameter), bright dots.] [Note: Results from cell cultures with bacterial contamination must, therefore, be interpreted with caution.] Stringent conditions for cross-reactivity testing were achieved by using a high concentration of the HSV-1 DFA Reagent or the HSV-2 DFA Reagent and high titers of microorganisms. The DFA Reagents were prepared at 1.5X the concentration that is provided in the kit. Depending on the particular virus, 500 to 715 TCID<sub>50</sub> viruses were inoculated into shell vial or multi-well plate cultures and incubated for 24 to 48 hours to yield a 1+ to 3+ infection, processed and stained with the 1.5X DFAs according to the procedure detailed in the product insert. Stained cells were examined at 200x magnification. Cell cultures were stained as confluent monolayers. Bacteria and yeast were cultured, processed as suspensions, then spotted on microscope slides (at CFUs ranging from 6.4x10<sup>4</sup> to 2.93x10<sup>7</sup>/well in a 10 µL dot, depending on the bacterium), then stained with the 1.5X DFAs according to the procedure in the product insert. Stained slides were examined at 400X magnification. Some microorganisms were procured from an external source as prepared microscope slides, intended to be used as positive controls for assays.

Virus Strains Tested for Cross Reactivity with D <sup>3</sup> HSV DFA Reagent					
Organism	Strain or Type	Inoculum (TCID <sub>50</sub> )	Organism	Strain or Type	Inoculum (TCID <sub>50</sub> )
Adenovirus	Type 1	715	Influenza B	Hong Kong	715
Adenovirus	Type 3	715	Influenza B	Maryland	715
Adenovirus	Type 5	715	Influenza B	Mass	715
Adenovirus	Type 6	715	Influenza B	Taiwan	715
Adenovirus	Type 7	715	Influenza B	GL	715
Adenovirus	Type 8	715	Influenza B	JH-001 isolate	715
Adenovirus	Type 10	715	Influenza B	Russia	715
Adenovirus	Type 13	715	RSV	Long	715
Adenovirus	Type 14	715	RSV	Wash	715
Adenovirus	Type 18	715	RSV	9320	715
Adenovirus	Type 31	715	Parainfluenza 1	C-35	715
Adenovirus	Type 40	715	Parainfluenza 2	Greer	715
Adenovirus	Type 41	715	Parainfluenza 3	C 243	715
Influenza A	Aichi	715	Parainfluenza 4a	M-25	715
Influenza A	Mal	715	Parainfluenza 4b	CH19503	715
Influenza A	Hong Kong	715	CMV	Towne	700
Influenza A	Denver	715	CMV	Davis	700
Influenza A	Port Chalmers	715	CMV	AD169	700
Influenza A	Victoria	715	VZV	Webster	500
Influenza A	New Jersey	715	VZV	Allen	500
Influenza A	PR	715	Epstein-Barr		
Influenza A	WS	715	Rubeola	Commercially available slides stained. <sup>a</sup>	
			Mumps		
Echovirus	Types 4, 6, 9, 11, 30, 34	Commercially available slides stained. <sup>a</sup>	HPV	Types 6, 11	Commercially available slides stained. <sup>a</sup>
Coxsackievirus	Types B1, B2, B3, B4, B5, B6	Commercially available slides stained. <sup>a</sup>			

Cell Lines Tested for Cross Reactivity with D <sup>3</sup> HSV DFA Reagent		
A549	MRHF	RhMK II
BGMK	Mv1Lu	pRK
HEp-2	NCI-H292	RD
LLC-MK2	pCMK	R-Mix
MDCK	pRhMK	Vero
MRC-5		WI-38

Microorganisms Tested for Cross Reactivity with D <sup>3</sup> HSV DFA Reagent			
BACTERIA	CFU TESTED	BACTERIA	CFU TESTED
Acinetobacter calcoaceticus	9.7 x 10 <sup>5</sup>	Salmonella typhimurium	1.7 x 10 <sup>5</sup>
Bordetella bronchiseptica	1.7 x 10 <sup>5</sup>	Staphylococcus aureus	1.0 x 10 <sup>7</sup>
Bordetella pertussis	4.6 x 10 <sup>5</sup>	Streptococcus agalactiae	9.6 x 10 <sup>5</sup>
Corynebacterium diphtheriae	2.5 x 10 <sup>5</sup>	Streptococcus pneumoniae	8.0 x 10 <sup>5</sup>
Escherichia coli	2.6 x 10 <sup>5</sup>	Streptococcus pyogenes	2.9 x 10 <sup>7</sup>
Gardnerella vaginalis	5.0 x 10 <sup>5</sup>	Acholeplasma laidlawi	~6 x 10 <sup>7</sup>
Haemophilis influenzae type A	9.3 x 10 <sup>5</sup>	Mycoplasma hominis	~6 x 10 <sup>3</sup>
Klebsiella pneumoniae	6.4 x 10 <sup>5</sup>	Mycoplasma orale	~6 x 10 <sup>4</sup>
Legionella pneumophila	6.5 x 10 <sup>4</sup>	Mycoplasma pneumoniae	~6 x 10 <sup>4</sup>
Moraxella cartarrhalis	6.4 x 10 <sup>4</sup>	Mycoplasma salivarium	~6 x 10 <sup>4</sup>
Neisseria gonorrhoeae	1.3 x 10 <sup>5</sup>	Ureaplasma urealyticum	~6 x 10 <sup>4</sup>
Proteus mirabilis	2.1 x 10 <sup>5</sup>	Chlamydia pneumoniae	Commercially available slides stained. <sup>a</sup>
Pseudomonas aeruginosa	1.0 x 10 <sup>7</sup>	Chlamydia trachomatis	Commercially available slides stained. <sup>a</sup>
Salmonella enteritidis	2.5 x 10 <sup>5</sup>		
YEAST		PROTOZOAN	
Candida glabrata	8.7 x 10 <sup>5</sup>	Trichomonas vaginalis	[Commercially available slides stained.]

**Clinical Performance**

Clinical studies have been conducted at three different laboratories where they compared the Diagnostic Hybrids, Inc. D<sup>3</sup> DFA Herpes simplex virus Identification and Typing Kit ("D<sup>3</sup> DFA HSV ID & Typing Kit") performance to that of currently marketed

<sup>a</sup> Test material is from commercially available prepared slides. Each positive well contained 10% to 50% reactive cells.

HSV identification kits ("Comparison Devices") using four hundred and one (401) prospectively collected specimens submitted for Herpes simplex culture. A combination of fresh (154) and frozen (247) specimens were tested. Three specimens from site 3 were not evaluated due to bacterial contamination of the monolayers, leaving 398 for analysis.

Two study sites used tube cultures and one used multi-well plates. Specimens were processed and cultured according to each laboratory's established procedures and testing performed according to the respective tests' instructions for use. The resulting stained cells were microscopically evaluated and results reported as HSV-1 positive, HSV-2 positive, or negative for detection of HSV.

Positive and Negative Percent Agreement between the Subject and Comparison test results were calculated and reported at 95% confidence interval.

Table of Combined Specimen Results from Three Study Sites

D <sup>3</sup> DFA HSV ID & Typing Kit	HSV-1 Comparison Device		HSV-2 Comparison Device		
	+	-	+	-	
	+	73	0	76	1
-	1	324	0	321	
Agreed	95% CI <sup>b</sup>		Agreed	95% CI	
Positive Percent Agreement <sup>c</sup> (PPA) =	98.6%	92.7% - 100%	100%	95.3% - 100%	
Negative Percent Agreement <sup>d</sup> (NPA) =	100%	98.9% - 100%	99.7%	98.3% - 100%	

<sup>1</sup> Specter, S., Hodinka, R. L., and Young, S.A. 2000, Clinical Virology Manual, Washington D.C., ASM Press, 420-424.

<sup>2</sup> Bryson, Y.J., M. Dillon, M. Lovett, G. Acura, S. Taylor, J.D. Cherry, L. Johnson, E. Weismeier, W. Growdeon, T. Creagh-Kirk and R. Keeney. 1983. "Treatment of first episodes of genital *Herpes simplex* virus infection with oral acyclovir: A randomized double-blind controlled trial in normal subjects". *New Eng. J. Med.*, 308: 916-921.

<sup>3</sup> Dulbecco, R. and H.S. Ginsberg. 1973. "Herpesviruses", Chapter 55 in *Microbiology*, Third Edition, D.D. Davis, et al. (eds.), Harper and Row, Hagerstown.

<sup>4</sup> Gleaves, C.A., D.J. Wilson, A.D. Wold and T.F. Smith. 1985. "Detection and Serotyping of *Herpes simplex* Virus in MRC-5 cells by use of centrifugation and monoclonal antibodies 16h post-inoculation". *J. Clin. Micro.*, 21: 29-32.

<sup>5</sup> Reeves, E.C., L. Corey, H.G. Adams, L.A. Vontver and K.K. Holmes. 1981. "Risk of recurrence after first episodes of genital herpes: relation to HSV type and antibody response". *New Eng. J. Med.*, 305: 315-319.

<sup>6</sup> Ashley, R.L., L. Corey, and W. E. Rawls. 1989. "*Herpes simplex* Viruses", Chapter 11 in *Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections*. Sixth Edition, N.J. Schmidt and R.W. Emmons, (eds), American Public Health Association, Inc., Washington, D.C.

<sup>7</sup> Gleaves, C.A., D.J. Wilson, A.D. Wold and T.F. Smith. 1985. "Detection and Serotyping of *Herpes simplex* Virus in MRC-5 cells by use of centrifugation and monoclonal antibodies 16h post-inoculation". *J. Clin. Micro.*, 21: 29-32.

<sup>8</sup> Moore, D.F. 1984. "Comparison of human fibroblast cells and primary rabbit kidney cells for isolation of *Herpes simplex* virus". *J. Clin. Micro.* 19: 548-549.

<sup>9</sup> Ashley, R.L., L. Corey, and W. E. Rawls. 1989. "*Herpes simplex* Viruses", Chapter 11 in *Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections*. Sixth Edition, N.J. Schmidt and R.W. Emmons, (eds), American Public Health Association, Inc., Washington, D.C.

<sup>b</sup> "95% CI" refers to 95% Confidence Intervals, which were calculated according to Exact method (Clopper, C. and S. Pearson, *Biometrika* 26:404-413, 1934).

<sup>c</sup> "Positive Percent Agreement", or "PPA", values were calculated according to  $\{[(\text{Total Number of Positive Results in Agreement by both Subject and Predicate Tests}) \div ((\text{Total Number of Positive Results in Agreement by both Subject and Predicate Tests}) + (\text{Number of Results Positive by Predicate but Negative by Subject}))]\}$  multiplied by 100%.

<sup>d</sup> "Negative Percent Agreement", or "NPA", values were calculated according to  $\{[(\text{Total Number of Negative Results in Agreement by both Subject and Predicate Tests}) \div ((\text{Total Number of Negative Results in Agreement by both Subject and Predicate Tests}) + (\text{Number of Results Negative by Predicate but Positive by Subject}))]\}$  multiplied by 100%.



Ms. Gail R. Goodrum  
Vice President, Regulatory and Quality Affairs  
Diagnostic Hybrids, Inc.  
350 West State Street  
Athens, OH 45701

Food and Drug Administration  
2098 Gaither Road  
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OCT 24 2007

Re: k070265  
Trade/Device Name: Diagnostic Hybrids D<sup>3</sup> DFA Herpes Simplex Virus Identification and Typing Kit  
Regulation Number: 21 CFR § 866.3305  
Regulation Name: Herpes simplex virus serological reagents  
Regulatory Class: II  
Product Code: GQN  
Dated: October 12, 2007  
Received: October 15, 2007

Dear Ms. Goodrum:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

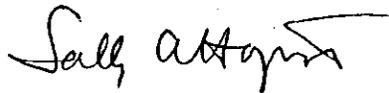
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070265

Device Name: Diagnostic Hybrids, Inc. D<sup>3</sup> DFA Herpes Simplex Virus Identification and Typing Kit

Indications for Use: The Diagnostic Hybrids, Inc. D<sup>3</sup> DFA Herpes Simplex Virus Identification and Typing Kit is intended for use in the qualitative detection and typing of human herpes simplex virus type 1 and type 2 (HSV-1 and HSV-2) in cell cultures by immunofluorescence using fluoresceinated monoclonal antibodies (MAbs). Negative results do not rule out an infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. Performance using direct specimen testing has not been evaluated.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

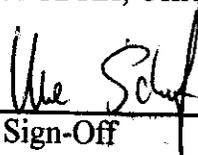
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K070265