JUL 2 4 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K091235

Establishment:

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Contact: Ken Pilgrim
Director – Quality / Regulatory

Prepared: 22 July, 2009

Regulatory Information:

Trade Name:	RAMP® RSV Assay
Common Name:	RSV immunological test system
Classification Name:	RSV immunological test system
Regulation Number:	866.3480, Respiratory syncytial virus serological reagents.
Classification:	Class I
Product Code:	GQG
Panel:	Microbiology
Predicate Device:	Quidel QuickVue RSV Assay

Intended Use

The RAMP RSV Assay is a qualitative immunochromatographic test for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in nasal wash/aspirate, nasopharyngeal aspirate and nasopharyngeal swab samples. It is an in vitro diagnostic assay that aids in the rapid diagnosis of RSV infections in symptomatic patients 21 years of age and younger. A negative test is presumptive and it is recommended that all negative results be confirmed by cell culture or direct specimen fluorescence assay (DSFA). Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional use.

Description of the Device:

The RAMP RSV Assay is a qualitative immunochromatographic test for the detection of Respiratory Syncytial Virus (RSV) in nasal wash/aspirate, nasopharyngeal aspirate, and nasopharyngeal swab samples from symptomatic patients 21 years of age and younger. A wash/aspirate or swab sample is mixed with Sample buffer and applied into the sample well of the Test Cartridge. The sample migrates along the strip. Fluorescent-dyed latex (test) particles, coated with anti-RSV antibodies bind to RSV antigens, if present in the sample. As the sample migrates along the strip, RSV-bound particles are captured at the RSV detection zone, and additional particles are captured at the internal standard zone.

Comparison of Technological Characteristics:

The RAMP RSV Assay and Quidel QuickVue RSV Assay are rapid immunochromatographic tests used for the detection of RSV virus antigen utilizing antibodies targeted toward the highly conserved, membrane-bound F-protein of the virus and thus do not require viable virus particles for detection. The RAMP and Quidel QuickVue RSV Assay tests provide results in approximately 15 minutes. Two methods used in the clinical laboratory are viral cell culture (culture) and Direct Specimen Fluorescence Assay (DSFA). Viral cell culture relies on the growth of cell lines and their infection with virus contained in the clinical sample. The time required to get a definitive result using these culture methods can be up to 30 days depending on the samples and methods used. DSFA relies on antigen detection and thus does not require viable virus particles in the sample to be evaluated. DSFA can be completed in several hours.

The RAMP RSV Assay and Quidel QuickVue RSV Assay are for use in the central laboratory, stat-lab and point-of-care facilities, while viral cell culture or DSFA are for use in the central laboratories due to their requirement for specialized equipment and reagents and highly trained operators.

These methods are indicated for use in the detection of RSV in nasal wash/aspirate, nasopharyngeal aspirate, and nasopharyngeal swab samples.

Summary of Studies:

ANALYTICAL PERFORMANCE

Analytical Sensitivity and Reactivity

The RAMP RSV Assay was evaluated for analytical sensitivity and reactivity after viral titer was determined by testing 6 strains of RSV (RSV A-Long, RSV A (A-2), RSV B CH93 (18)-18, RSV B Wash/18537/62, RSV B WV/14617/85, RSV B9320) at the LoD concentration in either viral transport media (VTM) to simulate a swab sample type or saline solution to simulate a wash sample type. Although the specific RSV strains causing infection in humans can vary year to year, all contain the conserved membrane-bound F-protein antigens targeted by the RAMP RSV Assay. Analytical sensitivity (LOD) ranged from $3.5x10^2$ to $>1.7x10^5$ $TCID_{50}$/mL.

RSV Sample	LoD Concentration ($TCID_{50}$/mL)	RAMP Result
A-Long in Saline	$6.5x10^3$	100% RSV Positive
A-Long in VTM	$2.5x10^3$	100% RSV Positive
A (A-2) in Saline	$1.0x10^3$	100% RSV Positive

RSV Sample	LoD Concentration ($TCID_{50}$/mL)	RAMP Result
A (A-2) in VTM	$1.2x10^3$	100% RSV Positive
B CH93(18)-18 in Saline	$3.5x10^2$	100% RSV Positive
B CH93(18)-18 in VTM	$3.5x10^2$	100% RSV Positive
B Wash/18537/62 in Saline	$7.0x10^3$	95% RSV Positive
B Wash/18537/62 in VTM	$6.0x10^3$	100% RSV Positive
B WV/14617/85 in Saline	$5.0x10^3$	100% RSV Positive
B WV/14617/85 in VTM	$2.5x10^3$	100% RSV Positive
B9320 in ZMC matrix	$> 1.7x10^5$	90% RSV Positive

Precision and Reproducibiity

The precision and reproducibility of the RAMP RSV Assay was evaluated using a panel consisting of a high negative RSV sample, a limit of detection (LoD) RSV sample (low positive), and a 2x LoD RSV sample (moderate positive). The RSV strain used to prepare the samples was RSV A (A-2) (ATCC VR-1540) following viral titer determinations. To evaluate reproducibility, multiple operators at multiple sites tested each of the three precision samples on 5 different days. Testing at Site 2 was performed in a point-of-care (POC) setting (near patient). At one site (Site 3), to evaluate precision, operators tested each of the three precision samples an additional 7 days for a total of 12 days.

There was 99.2% agreement (393/396) with the expected test results for all specimens tested, with no significant differences within run (same operator on same day) between run, operators or sites. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The overall RAMP Ratio %CV across all sites ranged from 13% to 16% depending on concentration tested.

	Sample	RSV High Negative	RSV Low Positive	RSV Moderate Positive	Total Agreement All (%)
	Viral Titer ($TCID_{50}$/mL)	200	1200	2400	
Site 1	Agreement	30/30	30/30	30/30	90/90 (100%)
	% CV	11%	11%	9%	
Site 2	Agreement	30/30	29/30	30/30	89/90 (98.9%)
	% CV	13%	14%	18%	
Site 3	Agreement	71/72	71/72	72/72	214/216 (99.1%)
	% CV	17%	12%	11%	
	Total Agreement	131/132 (99.2%)	130/132 (98.5%)	132/132 (100%)	393/396 (99.2%)
	95% CI	95.8 – 99.9%	94.6 – 99.6%	97.1 – 100%	97.8 – 99.7%
	Overall % CV	16%	13%	14%	

Interference

Whole blood and a number of other potentially interfering substances (medications and over the counter (OTC) products) that may be present naturally or artificially introduced in the nasal cavity or nasopharynx were evaluated in the RAMP RSV Assay. The substances were added to a negative sample (saline), an RSV LoD positive sample, and an RSV 2x LoD positive sample and tested in the RSV test at n=3 replicates. The RSV strain used to prepare the samples was RSV A (A-2) following titer determination. Interference was not evaluated with an RSV B strain. None of the substances tested at the concentrations indicated interfered with the test results of negative and positive RSV samples in the RAMP RSV Assay based on the RAMP Result acceptance criteria of 3/3 (Negative and 2x LOD) and ≥2/3 (LoD). The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The Percent of Mean Control Ratio values were calculated using these RAMP Ratios.

Substance Tested	Conc. Tested	Negative		RSV LoD		RSV 2x LoD	
		RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio
Control Saline (0.85%) only (No interfering substance)	N/A	Neg 3/3	100%	Pos 3/3	100%	Pos 3/3	100%
Whole Blood	2% v/v	Neg 3/3	118%	Pos 2/3	89%	Pos 3/3	86%
Mucin	1% w/v	Neg 3/3	123%	Pos 3/3	96%	Pos 3/3	94%
Scope® Mouthwash	40% v/v	Neg 3/3	117%	Pos 2/3	91%	Pos 3/3	85%
Good and Kind™ Mouthwash	40% v/v	Neg 3/3	122%	Pos 3/3	93%	Pos 3/3	83%
Cepacol® Mouth Wash	40% v/v	Neg 3/3	128%	Pos 2/3	90%	Pos 3/3	78%
Cepacol® Lozenge (Benzocaine)	30% w/v	Neg 3/3	115%	Pos 3/3	93%	Pos 3/3	69%
Fisherman's Friend® Throat Drop (Menthol)	30% w/v	Neg 3/3	107%	Pos 3/3	94%	Pos 3/3	80%
Rhinocort® Nasal Spray (Budesonide)	15% v/v	Neg 3/3	125%	Pos 3/3	102%	Pos 3/3	76%
Nasacort® Nasal Spray (Triamcinolone)	15% v/v	Neg 3/3	141%	Pos 3/3	98%	Pos 3/3	85%
Flonase® Nasal Spray (Fluticasone Furoate)	30% v/v	Neg 3/3	145%	Pos 3/3	105%	Pos 3/3	85%
Nasonex® Nasal Spray (Mometasone Furoate)	15% v/v	Neg 3/3	134%	Pos 3/3	94%	Pos 3/3	79%

Substance Tested	Conc. Tested	Negative		RSV LoD		RSV 2x LoD	
		RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio	RAMP Results	Percent of Mean Control Ratio
Tylenol® Tablets (4-Acetamidophenol)	20 mg/mL	Neg 3/3	96%	Pos 3/3	90%	Pos 3/3	81%
Aspirin® Tablets (Acetylsalicylic Acid)	30 mg/mL	Neg 3/3	127%	Pos 3/3	98%	Pos 3/3	80%
Chlor-Tripolon™ Tablets (Chloropheniramine)	10 mg/mL	Neg 3/3	106%	Pos 3/3	110%	Pos 3/3	98%
Benadryl™ Allergy Tablet (Diphenhydramine)	5 mg/mL	Neg 3/3	136%	Pos 3/3	107%	Pos 3/3	91%
Delsym® DM Cough Syrup (Dextromethorphan)	2 mg/mL	Neg 3/3	135%	Pos 3/3	121%	Pos 3/3	105%
Robitussin® Syrup (Guaiacol Glycerol Ether)	40 mg/mL	Neg 3/3	140%	Pos 3/3	89%	Pos 3/3	82%
Phenylpropanol-amine HCl (pure)	40 mg/mL	Neg 3/3	142%	Pos 3/3	105%	Pos 3/3	96%
Afrin® Nasal Spray (Oxymetazoline HCl)	0.05% v/v	Neg 3/3	103%	Pos 3/3	86%	Pos 3/3	76%
Neo-Synephrine® Nasal Spray (Phenylephrine HCl)	20 mg/mL	Neg 3/3	121%	Pos 3/3	87%	Pos 3/3	84%
Otrivin® Saline (NaCl w/preservatives)	1.4% w/v	Neg 3/3	122%	Pos 3/3	91%	Pos 3/3	94%
Rebetol® (Ribavirin)	100 ng/mL	Neg 3/3	116%	Pos 2/3	92%	Pos 3/3	82%
Relenza® (Zanamivir)	20 mg/mL	Neg 3/3	105%	Pos 3/3	89%	Pos 3/3	76%
Rimantadine HCl	500 ng/mL	Neg 3/3	118%	Pos 3/3	87%	Pos 3/3	85%
Tamiflu® (Oseltamivir Phosphate)	50 mg/mL	Neg 3/3	146%	Pos 3/3	127%	Pos 3/3	108%

Analytical Specificity (*Potential Cross-Reactive Organisms*)

The analytical specificity of the RAMP RSV Assay was determined by testing a panel consisting of 16 viruses and 17 bacteria that may be present in the nasal cavity or nasopharynx. Bacterial and viral isolates were tested at the concentrations listed after titer determination. None of the organisms tested gave a positive result in the RAMP RSV Assay. Note: RAMP RSV Assay potential cross-reactivity with *Chlamydophila pneumoniae* has not been determined.

Strain/Isolate	Concentration	RAMP result
Adenovirus, Type 1	10^5 $TCID_{50}$/mL	Negative
Adenovirus, Type 7a	10^5 $TCID_{50}$/mL	Negative
Human coronavirus, Strain OC43	10^5 $TCID_{50}$/mL	Negative
Human coronavirus, Strain 229E	10^5 $TCID_{50}$/mL	Negative
Cytomegalovirus	10^5 $TCID_{50}$/mL	Negative
Enterovirus, Type 71	10^5 $TCID_{50}$/mL	Negative
Epstein Barr Virus	10^5 $TCID_{50}$/mL	Negative
Human Parainfluenza, Type 1	10^5 $TCID_{50}$/mL	Negative
Human Parainfluenza, Type 2	10^5 $TCID_{50}$/mL	Negative
Human Parainfluenza, Type 3	10^5 $TCID_{50}$/mL	Negative
Influenza A, Brisbane/10/07	10^5 EID_{50}/mL	Negative
Influenza B, Ohio/01/06	10^5 $TCID_{50}$/mL	Negative
Measles	10^5 $TCID_{50}$/mL	Negative
Human metapneumovirus	10^5 $TCID_{50}$/mL	Negative
Mumps virus	10^5 $TCID_{50}$/mL	Negative
Human Rhinovirus, Strain 1A	10^5 $TCID_{50}$/mL	Negative
Bordetella pertussis	10^6 cfu/mL	Negative
Corynebacterium Sp.	10^6 cfu/mL	Negative
Escherichia coli	10^6 cfu/mL	Negative
Haemophilus influenzae	10^6 cfu/mL	Negative
Lactobacillus casei	10^6 cfu/mL	Negative
Legionella pneumophila	10^6 cfu/mL	Negative
Moraxella catarrhalis	10^6 cfu/mL	Negative
Mycobacterium tuberculosis, Avirulent	10^6 cfu/mL	Negative
Mycoplasma pneumoniae	10^6 cfu/mL	Negative
Neisseria meningitides	10^6 cfu/mL	Negative
Neisseria sicca	10^6 cfu/mL	Negative
Pseudomonas aeruginosa	10^6 cfu/mL	Negative
Staphylococcus aureus, Strain 176	10^6 cfu/mL	Negative
Staphylococcus epidermidis, Strain 78	10^6 cfu/mL	Negative
Streptococcus pneumoniae	10^6 cfu/mL	Negative
Streptococcus pyogenes	10^6 cfu/mL	Negative
Streptococcus salivarius	10^6 cfu/mL	Negative

Transport Media

Multiple lots of each of seven (7) commercially available transport media were evaluated for compatibility in the RAMP RSV Assay by testing a negative sample (transport media only), an RSV LoD positive sample and an RSV 2x LoD positive sample. The RSV strain used to prepare the samples was RSV A (A-2) following titer determination. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The %CVs were calculated for the RAMP Ratios. None of the tested transport media interfered with the performance of the RAMP RSV Assay.

Transport Media Tested	RAMP Results		
	Negative	RSV LoD	RSV 2x LoD
Copan Universal Transport Media (UTM)	100% Neg	100% Pos	100% Pos
Remel M4 Media	100% Neg	100% Pos	100% Pos
Remel M4-RT Media	100% Neg	100% Pos	100% Pos
Remel M5 Media	100% Neg	100% Pos	100% Pos
Starplex Transport Media	100% Neg	100% Pos	100% Pos
0.85% Saline Solution	100% Neg	93% Pos	100% Pos
Phosphate Buffered Saline (PBS) Solution	100% Neg	93% Pos	100% Pos
Average RAMP Ratio % CV	12%	16%	14%

Sample Collection Swabs

Four swab materials were evaluated for compatibility in the RAMP RSV Assay by testing a negative sample (swab alone with no virus present), an RSV LoD positive sample and an RSV 2x LoD positive sample in the RSV test. The RSV strain used to prepare the samples was RSV A (A-2) following titer determination. Each swab was dosed with the appropriate sample and extracted into Copan Universal Transport Media prior to testing in the RAMP RSV Assay. The RAMP RSV Assay is a qualitative assay based on numerical RAMP Ratio values. The %CVs were calculated for the RAMP Ratios. The negative sample (swab alone) tested negative and all 2x LoD samples tested positive. None of the swabs tested interfered with the performance of the RAMP RSV Assay. Note: In general, calcium alginate swabs are not recommended because they may be cytotoxic to cells and cause viral culture assay inhibition.[1]

Swab Material Tested	RAMP Results		
	Negative	RSV LoD	RSV 2x LoD
Foam	100% Neg	100% Pos	100% Pos
Polyester	100% Neg	67% Pos	100% Pos

Rayon	100% Neg	67% Pos	100% Pos
Nylon	100% Neg	100% Pos	100% Pos
Average RAMP Ratio % CV	9%	21%	21%

CLINICAL PERFORMANCE

Method Comparison

The performance of the RAMP RSV Assay was compared to cell culture and DSFA in a prospective study conducted as part of a multi-center trial during the 2008-2009 RSV season. Eight (8) independent centers located in distinct geographical regions across the United States (NY, MO(2), MD, OH(2), MA, AR) evaluated the RAMP RSV Assay in parallel with cell culture and DSFA. Testing staff included both laboratory and non-laboratory personnel, and two centers (MO, AR) also performed testing in point of care settings (near patient). The sites included an Emergency Department and Pediatric Testing Unit. One thousand, two hundred and seventy nine (1279) fresh specimens were collected from subjects 21 years of age and younger. Of these specimens, valid results were obtained from 1140, with an approximately equal mix of male and female patients.

Clinical Sensitivity and Specificity

Overall Sensitivity and Specificity Relative to Culture and DSFA

	N = 1140
Sensitivity	87.3%
Specificity	95.6%

Sensitivity and Specificity by Age Relative to Culture and DSFA

NP Swab (All Ages)			
Culture / DSFA	**RAMP**		
	Positive	**Negative**	**Total**
Positive	112	15	127
Negative	7*	257	264
Total	119	272	391
			95% CI
Sensitivity	88.2%		81.4 – 92.7
Specificity		97.4%	94.6 – 98.7

* 1 was positive by the RAMP RSV Assay and by the Prodesse ProFlu RT-PCR analysis.

NP Swab (Age <6)			
Culture / DSFA	RAMP		
	Positive	Negative	Total
Positive	108	14	122
Negative	2	184	186
Total	110	198	308
			95% CI
Sensitivity	88.5%		81.7 – 93.0
Specificity		98.9%	96.2 - 99.7

NP Aspirate (All Ages)			
Culture / DSFA	RAMP		
	Positive	Negative	Total
Positive	168	29*	197
Negative	15**	291	306
Total	183	320	503
			95% CI
Sensitivity	85.3%		79.7 – 89.6
Specificity		95.1%	92.1 – 97.0

* 8 were negative by the RAMP RSV Assay and by an investigational RT-PCR.
** 3 were positive by the RAMP RSV Assay and by an investigational RT-PCR.

NP Aspirate (Age <6)			
Culture / DSFA	RAMP		
	Positive	Negative	Total
Positive	165	27	192
Negative	9	245	254
Total	174	272	446
			95% CI
Sensitivity	85.9%		80.3 – 90.1
Specificity		96.5%	93.4 – 98.1

Nasal Wash / Aspirate (All Ages)			
Culture / DSFA	RAMP		
	Positive	Negative	Total
Positive	98	11*	109
Negative	9**	128	137
Total	107	139	246
			95% CI
Sensitivity	89.9%		82.8 – 94.3
Specificity		93.4%	88.0 – 96.5

* 1 was negative by the RAMP RSV Assay and by an investigational RT-PCR.
** 1 was positive by the RAMP RSV Assay and by an investigational RT-PCR.

Nasal Wash / Aspirate (Age <6)			
Culture / DSFA	RAMP		
	Positive	Negative	Total
Positive	96	11	107
Negative	8	116	124
Total	104	127	231
			95% CI
Sensitivity	89.7%		82.5 – 94.2
Specificity		93.6%	87.8 – 96.7

Additional Sample Analysis

Samples for which the results of DSFA, culture and RAMP RSV did not all agree were evaluated with PCR. Results of sample testing showed that nine (9) subjects with a positive reference and a negative RAMP result (false negatives) were PCR negative and five (5) subjects with a negative reference and a positive RAMP result (false positives) were PCR positive. These data have not been incorporated in the sensitivity and specificity tables shown above.

REFERENCES:

1. Lauer and Masters, Journal of Clinical Microbiology, 1988, January; 26(1): 54–56

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JUL 2 4 2009

Ken L. Pilgrim
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Re: K091235
Trade/Device Name: RAMP RSV Assay
Regulation Number: 21 CFR 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: Class I
Product Code: GQG
Dated: April 23, 2009
Received: April 27, 2009

Dear Mr. Pilgrim:

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).
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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K091235

Device Name: RAMP® RSV Assay

Indications for Use:

The RAMP RSV Assay is a qualitative immunochromatographic test for the detection of Respiratory Syncytial Virus (RSV) F-protein antigens in nasal wash/aspirate, nasopharyngeal aspirate and nasopharyngeal swab samples. It is an in vitro diagnostic assay that aids in the rapid diagnosis of RSV infections in symptomatic patients 21 years of age and younger. A negative test is presumptive and it is recommended that all negative results be confirmed by cell culture or direct specimen fluorescence assay (DSFA). Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k091235