K131813

510(k) Summary

Applicant:

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SEP 06 2013

Date of preparation of 510(k) summary:

June 11, 2013

Device Name:

Trade name – **Quidel Molecular RSV + hMPV Assay**
Classification name – Respiratory viral panel multiplex nucleic acid assay
Product Code – OEM, OCC
Regulation – 21 CFR 866.3980
Classification – Class II

Device Description:

The Quidel Molecular RSV + hMPV Assay detects viral nucleic acids that have been extracted from a patient sample using the bioMérieux NucliSENS easyMAG automated extraction platform. A multiplex RT-PCR reaction is carried out under optimized conditions in a single tube generating amplicons for each of the target viruses present in the sample. This reaction is performed utilizing the Cepheid SmartCycler II, the Applied Biosystems 7500 Fast Dx, or the Life Technologies QuantStudio Dx. Identification of RSV, hMPV, and the process control (PRC) occurs by the use of target-specific primers and fluorescent-labeled probes that hybridize to conserved regions in the genomes of RSV and hMPV and the PRC.

The following is a summary of the procedure:

1. **Sample Collection:** Obtain nasal or nasopharyngeal swab specimens using standard techniques from symptomatic patients. Transport, store, and process these specimens according to established laboratory procedures.

2. **Nucleic Acid Extraction:** Extract nucleic acids from the specimens with the BioMérieux NucliSENS easyMAG System following the manufacturer's instructions and using the appropriate reagents.

   Prior to the extraction procedure, add 20 µL of the PRC to each 180 µL aliquot of specimen. The PRC serves to monitor inhibitors in the extracted specimen, assures that adequate amplification has taken place, and confirms that the nucleic acid extraction was sufficient.

3. **Rehydration of Master Mix:** Rehydrate the lyophilized Master Mix using the Rehydration Solution. The Master Mix contains oligonucleotide primers and fluorophore/quencher-labeled probes that target conserved regions of RSV and hMPV, as well as the PRC.

4. **Nucleic Acid Amplification and Detection:** Add 15 µL of the rehydrated Master Mix to each reaction tube or plate well. Then add 5 µL of extracted nucleic acids (specimen with PRC) to the plate well or appropriately labeled reaction tube. Place the tube or plate into the SmartCycler II, 7500 Fast Dx, or the Life Technologies QuantStudio Dx instruments.

   Once the reaction tube or plate is added to the instrument, initiate the assay protocol. This protocol initiates reverse transcription of the RNA targets, generating complementary DNA and the subsequent amplification of the target amplicons. The Quidel Molecular RSV + hMPV Assay is based on TaqMan chemistry and uses an enzyme with reverse transcriptase, DNA polymerase, and 5'-3' exonuclease activities. During DNA amplification, this enzyme cleaves the probe bound to the complementary DNA sequence, separating the quencher dye from the reporter dye. This step generates an increase in fluorescent signal upon excitation by a light source of the appropriate wavelength. With each cycle, additional dye molecules are separated from their quenchers resulting in additional signal. If sufficient fluorescence is achieved, the sample is reported as positive for the detected nucleic acid.

Intended Use:

The Quidel Molecular RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to

aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

The Quidel Molecular RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio™ Dx RT-PCR Instrument, the Applied Biosystems® 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler® II System.

Conditions for Use:

For prescription use only.

Device Comparison

The Quidel Molecular RSV + hMPV Assay was compared to two FDA cleared RT-PCR assays. The characteristics of Quidel Molecular RSV + hMPV Assay ("Subject Device") and the Prodesse ProFlu + and Pro hMPV+ ("Predicate Devices") are described in the table below:

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+ (K092500)	**Predicate Device** Prodesse Pro hMPV+ (K082688)
Intended Use	The Quidel Molecular RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial	The ProFlu™+ Assay is a multiplex Real-Time PCR (RT-PCR) *in vitro* diagnostic test for the rapid and qualitative detection and discrimination of Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus	The Pro hMPV+ Assay is a Real-Time RT-PCR *in vitro* diagnostic test for the qualitative detection of human Metapneumovirus (hMPV) nucleic acid isolated and purified from nasopharyngeal swab (NP) specimens

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+ (K092500)	**Predicate Device** Prodesse Pro hMPV+ (K082688)
	virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV. Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management	(RSV) nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens obtained from symptomatic patients. This test is intended for use to aid in the differential diagnosis of Influenza A, Influenza B and RSV viral infections in humans and is not intended to detect Influenza C. Negative results do not preclude influenza or RSV virus infection and should not be used as the sole basis for treatment or other management decisions. Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.	obtained from individuals exhibiting signs and symptoms of acute respiratory infection. This assay targets a highly conserved region of the Nucleocapsid gene of hMPV. The detection of hMPV nucleic acid from symptomatic patients aids in the diagnosis of human respiratory hMPV infection if used in conjunction with other clinical and laboratory findings. This test is not intended to differentiate the four genetic sub-lineages of hMPV. Negative results do not preclude hMPV infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+ (K092500)	**Predicate Device** Prodesse Pro hMPV+ (K082688)
	decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection. The Quidel Molecular RSV + hMPV Assay can be performed using the Life Technologies QuantStudio™ Dx RT-PCR Instrument, the Applied Biosystems® 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler® II System.	Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation (2006-2007 respiratory season). Performance characteristics for Influenza A were confirmed when Influenza A/H1, Influenza A/H3, and Influenza A/2009 HiNi were the predominant Influenza A viruses in circulation (2008 and 2009). When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with	

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+ (K092500)	**Predicate Device** Prodesse Pro hMPV+ (K082688)
		appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	
Assay Target	RSV, hMPV	Influenza A virus, influenza B virus, RSV	hMPV
Sample Types	Nasal swab, nasopharyngeal swab	Nasopharyngeal swab	Nasopharyngeal swab
Instrument/Assay Platform	Life Technologies QuantStudio Dx RT-PCR Instrument, the Applied Biosystems 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler II System	Cepheid SmartCycler II System	Cepheid SmartCycler II System
Assay Controls	An internal RNA control is provided	Influenza A, Influenza B, RSV A, RSV B positive RNA transcript controls and an internal RNA control are provided	hMPV positive RNA transcript control and an internal RNA control are provided
Extraction Methods	bioMérieux NucliSENS easyMAG System	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit or	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit or

Subject Device and Comparator Device Comparison			
Item	**Subject Device** Quidel Molecular RSV + hMPV Assay	**Predicate Device** Prodesse ProFlu+ (K092500)	**Predicate Device** Prodesse Pro hMPV+ (K082688)
		the bioMérieux NucliSENS easyMAG System	the bioMérieux NucliSENS easyMAG System
Assay Methodology	RT-PCR-based system for detecting the presence or absence of viral RNA in clinical specimens	RT-PCR-based system for detecting the presence or absence of viral RNA in clinical specimens	RT-PCR-based system for detecting the presence or absence of viral RNA in clinical specimens
Viral Targets	RSV: L viral polymerase and NS2 genes hMPV: RNA polymerase gene	Influenza A: Matrix Gene; Influenza B: Non-structural NS1 and NS2 RSV A and RSV B: polymerase	Nucleocapsid gene

Analytical Performance:

Reproducibility:

The reproducibility of the Quidel Molecular RSV + hMPV Assay using the Life Technologies QuantStudio Dx Real-Time PCR Instrument was evaluated at 3 laboratory sites (two external, one in-house). Reproducibility was assessed using a panel of 4 simulated samples that include medium positive, low positive, high negative, and negative samples. Separate panels were constructed for RSV and hMPV, using the RSV-A Long strain and hMPV-A2 strain respectively. Panels and controls were extracted using the bioMérieux NucliSENS easyMAG System and tested at each site by 2 operators for 5 days (triplicate testing x 2 operators x 5 days x 3 sites = 90 results per level for each virus). The LoD values are based on the values obtained in the LoD study.

Reproducibility Results –QuantStudio Dx										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
RSV High Negative 0.3x	15/30	37.6	3.7	1/30	37.7	N/A	23/30	36.7	3.7	39/90

Reproducibility Results –QuantStudio Dx										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
LoD										
RSV Low Positive 2x LoD	30/30	32.3	5.3	29/30	34.9	5.0	30/30	32.1	2.7	89/90
RSV Med Positive 5x LoD	30/30	30.3	1.9	30/30	31.5	5.5	30/30	29.9	1.6	90/90
RSV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
RSV Negative Control	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
RSV Positive Control	30/30	30.9	1.7	30/30	33.0	5.1	30/30	31.9	10.2	90/90
hMPV High Negative 0.15x LoD	20/30	35.9	4.0	11/30	35.2	5.9	21/30	36.6	4.0	52/90
hMPV Low Positive 2x LoD	30/30	30.3	5.0	30/30	30.2	2.5	30/30	30.4	2.1	90/90
hMPV Med Positive 5x LoD	30/30	28.9	2.0	30/30	28.4	1.2	30/30	28.3	3.7	90/90
hMPV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90
hMPV Negative	0/30	N/A	N/A	0/30	N/A	N/A	0/30	N/A	N/A	0/90

Reproducibility Results –QuantStudio Dx										
Panel Member ID	Site 1			Site 2			Site 3			Total Results
	Results	AVE Ct	%CV	Results	AVE Ct	%CV	Results	AVE Ct	%CV	
Control										
hMPV Positive Control	30/30	28.7	0.6	30/30	28.1	2.3	30/30	28.3	4.4	90/90

The data from the combined sites indicates that the Quidel Molecular RSV + hMPV Assay generates reproducible results for RSV and hMPV when tested with the Life Technologies QuantStudio Dx.

Combined Sites RSV						
	5X LoD	2X LoD	0.3X LoD	Negative	Positive Control	Negative Control
Detection %	100%	98.9%	43.3%	0%	100%	0%
Ave.	30.6	33.1	37.1	N/A	31.9	N/A
STDEV	1.3	1.9	1.4	N/A	2.3	N/A
%CV	4%	6%	4%	N/A	7%	N/A

Combined Sites hMPV						
	5X LoD	2X LoD	0.15X LoD	Negative	Positive Control	Negative Control
Detection %	100%	100%	57.8%	0%	100%	0%
Ave.	28.6	30.3	36.0	N/A	28.3	N/A
STDEV	0.8	1.0	1.6	N/A	0.8	N/A
%CV	3%	3%	4%	N/A	3.0%	N/A

Precision

The precision of the Quidel Molecular RSV + hMPV Assay using the Life Technologies QuantStudio Dx Real-Time PCR Instrument was determined using quantified dilutions of RSV and hMPV stocks (10X, 3X, and 0.15X LoD). These dilutions were tested by two operators for twelve days. The data from this study indicates that when tested on the Life Technologies QuantStudio Dx Real-Time PCR Instrument, the Quidel Molecular RSV + hMPV Assay produces repeatable, precise results.

Limit of Detection

The analytical sensitivity (limit of detection or LoD) of the Quidel Molecular RSV + hMPV Assay using the Life Technologies QuantStudio Dx Real-Time PCR Instrument was determined using quantified ($TCID_{50}$/mL) cultures of 2 RSV strains (RSV-A Long

and RSV-B Washington strains) and 4 hMPV strains (hMPV_A1, hMPV_A2, hMPV_B1, and hMPV_B2 strains) serially diluted in negative nasal matrix. Each dilution was extracted in replicates of 20 per concentration of virus using the bioMérieux NucliSENS easyMAG System. Analytical sensitivity (LoD) is defined as the lowest concentration at which 95% of all replicates tested positive.

Virus	LoD TCID50/mL QuantStudio Dx
RSV A	6.29E-01
RSV B	2.25E-01
hMPV-A1	8.73E+00
hMPV-A2	2.91E+00
hMPV-B1	2.25E+00
hMPV-B2	2.25E+00

Carryover and Cross-contamination Studies

In an internal study there was no evidence of carry-over/cross contamination on the QuantStudio Dx thermocycler platform when the Quidel Molecular RSV + hMPV Assay was used to detect the presence of high concentrations of RSV-B and hMPV-A1 (2.57E+06 and 3.16E+07, respectively) extracted with the BioMérieux NucliSENS easyMAG System.

Competitive Interference

A study was performed to determine whether competitive interference exists when both RSV and hMPV analytes are present in the same reaction when tested on the Life Technologies QuantStudio Dx Real-Time PCR Instrument. Results showed that at 2X LoD hMPV was inhibited at a level 10,000X above LoD of RSV-A when tested on the QuantStudio Dx. Inhibition was also seen at this concentration on the Applied Biosystems 7500 Fast Dx and Cepheid SmartCycler II (K122189).

Analytical Reactivity (Inclusivity):

Please see K122189 for Analytical Reactivity (Inclusivity) studies.

Analytical Specificity (Cross-Reactivity):

Please see K122189 for Analytical Specificity (Cross-Reactivity) studies.

Clinical Performance:

Performance characteristics of the Quidel Molecular RSV + hMPV Assay using the Life Technologies QuantStudio Dx Real-Time PCR Instrument was established during a prospective study during the 2013 respiratory virus season (January to March 2013). Seven hundred and thirteen (713) nasal or nasopharyngeal swab specimens that were collected and extracted fresh for routine respiratory virus testing were used for this study at three (3) sites across the United States. A single specimen was collected per patient.

The specimens were extracted with the bioMérieux NucliSENS easyMAG System and tested with the Quidel Molecular RSV + hMPV Assay using the Life Technologies QuantStudio Dx RT-PCR Instrument. Sites 1 and 2 also extracted each specimen with the bioMérieux NucliSENS easyMAG System and tested with the comparator devices. Aliquots of each specimen from Site 3 were sent to Site 1 for testing with the comparator devices. Sample extracts were stored at -70°C until the time of testing.

Combined Clinical Site Data:

Seven hundred and thirteen (713) nasal or nasopharyngeal swab specimens were tested by both the subject and comparator device for RSV viral RNA. A total of thirteen (13) invalid specimens were removed from the analysis. Two (2) of these specimens were invalid on initial and repeat testing with the subject device (0.3%). Eleven (11) specimens were invalid on initial and repeat testing on the comparator device (1.5%). The table below details the results for the remaining seven hundred (700) specimens.

RSV			
	Comparator: FDA Cleared RT-PCR device		
Quidel Molecular	Positive	Negative	Total
Positive	105	11	116
Negative	7	577	584
Total	112	588	700
			95% CI
Positive Percent Agreement	105/112	93.8%	87.7% to 96.9%
Negative Percent Agreement	577/588	98.1%	96.7% to 99.0%

Seven hundred and thirteen (713) nasal or nasopharyngeal swab specimens were tested by both the subject and comparator device for hMPV viral RNA. A total of six (6) invalid specimens were removed from the analysis. Two (2) of these specimens were invalid on initial and repeat testing with the subject device (0.3%). Four (4) specimens were invalid on initial and repeat testing on the comparator device (0.6%). The table below details the results for the remaining seven hundred and seven (707) specimens.

hMPV			
	Comparator: FDA Cleared RT-PCR device		
Quidel Molecular	Positive	Negative	Total
Positive	55	4	59
Negative	1	647	648
Total	56	651	707
			95% CI
Positive Percent Agreement	55/56	98.2%	90.6% to 99.7%
Negative Percent Agreement	647/651	99.4%	98.4% to 99.8%

Conclusions:

The results of the analytical and clinical performance studies submitted in this premarket notification are complete and demonstrate that, when performed on the Life Technologies QuantStudio Dx RT-PCR Instrument, the Quidel Molecular RSV + hMPV Assay was substantially equivalent compared to the two FDA 510(k) cleared molecular devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 6, 2013

QUIDEL CORPORATION
C/O RONALD H. LOLLAR
SENIOR DIRECTOR CLINICAL AND QUALITY AFFAIRS
DIAGNOSTIC HYBRIDS, INC.
1055 EAST STATE STREET, SUITE 100
ATHENS OH 45701

Re: K131813
Trade/Device Name: Quidel Molecular RSV + hMPV Assay
Regulation Number: 21 CFR 866.3980
Regulation Name: Respiratory viral panel multiplex nucleic acid assay
Regulatory Class: II
Product Code: OEM, OCC
Dated: June 19, 2013
Received: June 20, 2013

Dear Mr. Lollar:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K131813

Device Name: Quidel Molecular RSV + hMPV Assay

Indications for Use:

The Quidel Molecular RSV + hMPV Assay is a multiplex Real-Time PCR (RT-PCR) assay for the qualitative detection and identification of respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) ribonucleic acid (RNA) extracted from nasal and nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection. This *in vitro* diagnostic test is intended to aid in the differential diagnosis of RSV and hMPV infections in humans in conjunction with clinical and epidemiological risk factors. This test is not intended to differentiate the two subtypes of RSV or the four genetic sub-lineages of hMPV.

Negative results do not preclude RSV infection and/or hMPV infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions.

Conversely, positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing and clinical presentation must be considered in order to obtain the final diagnosis of respiratory viral infection.

The Quidel Molecular RSV + hMPV Assay can be performed using either the Life Technologies QuantStudio™ Dx RT-PCR Instrument, the Applied Biosystems® 7500 Fast Dx RT-PCR Instrument, or the Cepheid SmartCycler® II System.

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 IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Tamara V. Feldblyum -S
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