

MAY 17 2011

SECTION 5: 510(k) Summary of Safety and Effectiveness**5.1 Sponsor**

Rapid Pathogen Screening, Inc.
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Sarasota, FL 34240
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Contact Person: Douglas Bueschel
Vice President, Quality Assurance & Regulatory Affairs

5.2 Date Prepared

May 16, 2011

5.3 Device Information

Proprietary Name:	RPS Adeno Detector Plus™
Common Name:	RPS Adeno Detector Plus
Device Category:	Class I
Product Code:	GOD
Regulation Number:	866.3020, Adenovirus Serological Reagents [Antigens, Cf (including control)]

5.4 Predicate Device

Rapid Pathogen Screening, Inc.; RPS Adeno Detector (K052092)

5.5 Device Description*Components-*

The RPS Adeno Detector Plus™ consists of three (3) parts: a Sample Collector, an immunoassay test strip in a plastic Test Cassette housing, and a Buffer. The Sample Collector is used to take a sample of ocular fluid. The separately packaged and sterile Sample Collector has a contoured end with a Dacron fleece to collect the samples. The plastic housing of the Test Cassette body protects the strip from unintended physical influence. Additionally the housing guarantees correct sample transfer onto the lateral flow assay strip. The Buffer is a buffered salt solution containing proteins, detergents and preservatives. The Buffer functions as the solution that initiates the test, extracts the Adenoviral

proteins, filters unwanted cellular debris, and transports the immune complex and the control conjugate to the Test and Control Lines on the test strip membrane.

Mechanism of action –

RPS Adeno Detector Plus™ is based on the principle of lateral flow immunoassays using Direct Sampling Micro-filtration technology. Viral particles or virus antigens are captured by an antigen specific antibody. A single monoclonal antibody highly specific to the Adenoviral hexon protein is labeled with colloidal gold and also is immobilized as the Test Line.

The speed and simplicity of the test enables more appropriate and timely treatment for the patient.

5.6 Intended Use

The RPS Adeno Detector Plus is a rapid immunoassay test for the visual, qualitative *in vitro* detection of Adenoviral antigens (hexon protein) directly from human eye fluid. The test is intended for professional use as an aid in the rapid differential diagnosis of acute conjunctivitis.

Negative results do not preclude Adenovirus infection nor are they intended to rule out other microbial-caused infections of the conjunctiva, and should not be used as the sole basis for treatment or other management decisions.

5.7 Substantial Equivalence

RPS Adeno Detector Plus has substantially equivalent indications to the RPS Adeno Detector (K052092) predicate in that they are indicated for the rapid, visual qualitative *in vitro* detection of Adenovirus and its serotypes directly from eye fluid on the conjunctiva.

The RPS Adeno Detector Plus uses the same technology as RPS Adeno Detector. The subject device and the predicate device are made from materials which have demonstrated satisfactory biocompatibility and are sterile, single use devices.

5.8 Performance Testing

Biocompatibility Testing – supported by literature.

In vitro Testing –

The RPS Adeno Detector Plus completed a series of analytical bench tests for sensitivity and specificity.

Animal Studies – Not Applicable.

Clinical Studies –

A Clinical Trial was performed by Rapid Pathogen Screening, Inc. to compare the sensitivity and specificity of the RPS Adeno Detector Plus at detecting the presence of Adenovirus as compared to Cell Culture. The study design was a prospective, sequential, masked, clinical trial with eight (8) Clinical Trail Sites.

5.9 Clinical Results

N = 128		Cell Culture	
		+	-
RPS Adeno Detector Plus	+	28	4
	-	3	93
Sensitivity		90% (28/31) 95% CI [74.2-98.0]	
Specificity		96% (93/97) 95% CI [89.8-98.9]	
Negative Predictive Value		97% (93/96) 95% CI [91.1-99.3]	
Positive Predictive Value		88% (28/32) 95% CI [71.0-96.5]	

6.0 Conclusion

Rapid Pathogen Screening, Inc. believes that, as a result of the *in vitro* testing, clinical testing, and literature references supporting biocompatibility, the RPS Adeno Detector Plus is for the rapid, visual, qualitative *in vitro* detection of Adenovirus and its serotypes directly from eye fluid on the conjunctiva. The RPS Adeno Detector Plus is

substantially equivalent to the predicate device, RPS Adeno Detector (K052092).

5-4



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Rapid Pathogen Screening, Inc.
c/o Robert Sambursky, MD
Chief Medical Officer
7227 Delainey Court
Sarasota, FL 34240

Re: K110722

Trade/Device Name: RPS Adeno Detector PlusTM
Regulation Number: 21 CFR 866.3020
Regulation Name: Adenovirus serological reagents
Regulatory Class: Class I
Product Code: GOD
Dated: March 7, 2011
Received: March 15, 2011

MAY 17 2011

Dear Dr. Sambursky:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/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): K110722

Device Name: RPS Adeno Detector Plus™

Indications For Use:

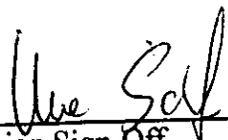
The RPS Adeno Detector Plus is a rapid immunoassay test for the visual, qualitative in-vitro detection of Adenoviral antigens (hexon protein) directly from human eye fluid. The test is intended for use as an aid in the rapid differential diagnosis of acute conjunctivitis.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 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



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k 110722