

K081938

MAY - 1 2009

Acetaminophen L3K<sup>®</sup> Assay

Product Cat. No. 506-10 & 506-30

510(K) SUMMARY

**Introduction:** 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.

**Submitter:** Genzyme Diagnostics P.E.I. Inc.  
70 Watts Avenue  
Charlottetown, P.E.I.  
Canada C1E 2B9  
(Tel: ) (902)566-1396  
(Fax: ) (902)628-6504

Contact Person: Penny White

Date Prepared: June 1, 2008

**Device Name:** Tradename: Acetaminophen L3K<sup>®</sup> Assay  
FDA Regulation Name: 862.3030 Colorimetry, Acetaminophen  
FDA Product Code: LDP

**Predicate Device:** Genzyme Diagnostics P.E.I. Inc. (K042330)

**Device Description:** For the quantitative measurement of acetaminophen in serum and plasma. Measurement of acetaminophen is used in the diagnosis and treatment of acetaminophen overdose toxicity. Excessive amounts of acetaminophen leads to hepatotoxicity and nephrotoxicity. In acute overdosage, acetaminophen can cause severe hepatic damage leading to hepatic failure if untreated.

Reagent is a two-part liquid in plastic bottles packaged in the appropriate box.

**Intended Use** For the quantitative measurement of acetaminophen in serum and plasma. Measurement of acetaminophen is used in the diagnosis and treatment of severe liver damage caused by overdose toxicity. Excessive amounts of acetaminophen leads to hepatotoxicity and nephrotoxicity. In acute overdosage, acetaminophen can cause severe hepatic damage leading to hepatic failure if untreated.  
For IN VITRO diagnostic use.

**Comparison to  
Predicate Device:**

Description of the Item Being Compared:

For the In Vitro quantitative measurement

Acetaminophen Enzyme Reagent (R1): buffer (pH 8.6 at 25 °C ) 0.2 mmol/L  $MnCl_2 \cdot 4H_2O$ ,  $\geq 0.9$  KU/L Acyl Amidohydrolase, surfactant, preservatives.

Acetaminophen Color Reagent (R2): 0.1 mol/L sodium carbonate buffer (pH 12.2 at 25 °C ), 30 mmol/L 8-hydroxyquinoline-5-sulfonic acid, surfactant, preservatives.

Acetaminophen Standard: buffer (pH 5.0 at 25 °C ), 1000 $\mu$ mol/L (15.1 mg/dL) acetaminophen, preservatives.

Similarities:

The submission device and the predicate device have the same intended use.

The submission device and the predicate device both use Aryl Acylamidase enzyme method in acetaminophen measurement.

The submission device and the predicate device have the same oxidative coupling method.

Differences:

The predicate device uses a different chromophore in the oxidative coupling reaction during color development.

The predicate devices uses 8 hydroxyquinoline and the submission device uses 2,5 dimethylphenol.

**Comments on  
Substantial  
Equivalence:**

Testing results demonstrate that the Acetaminophen L3K<sup>®</sup> Assay is equivalent to the predicate device. Method comparison results provided the following:

Serum

Deming regression using NCCLS EP9-A2.

A comparison was made between this method and a similar acetaminophen method using 100 samples in **serum** ranging from 26 to 2361  $\Phi$ mol/L. The correlation coefficient was 0.9999. Deming regression analysis gave the following equation:

This method = 1.060(reference method) + 4.6  $\Phi$ mol/L

Confidence interval is 95%. Correlation coefficient is 0.9999. The amount of scatter around the estimate regression line is 8.9. The approach is not different from the predicate device.

### **Plasma**

A comparison was made between **serum** and **plasma** using 25 samples ranging from 30 to 2441 µmol/L. The correlation coefficient was 0.9999. Linear regression analysis gave the following equation:

This method (plasma) = 0.999 [This method (serum)] -2.2 µmol/L

### **Conclusion:**

Genzyme Diagnostics P.E.I. Inc. Acetaminophen L3K<sup>®</sup> Assay is substantially equivalent in principle and performance to the predicate product.

Penny White  
*Regulatory Affairs Coordinator*  
Genzyme Diagnostics P.E.I. Inc.



MAY - 1 2009

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Genzyme Diagnostics P.E.I. Inc.  
c/o Ms. Penny J. White  
Regulatory Affairs Coordinate  
70 Watts Avenue  
Charlottetown, Prince Edward Island  
Canada C1E 2B9

Re: k081938  
Trade/Device Name: Acetaminophen L3K Assay  
Regulation Number: 21 CFR 862.3030  
Regulation Name: Acetaminophen test system  
Regulatory Class: Class II  
Product Code: LDP  
Dated: April 8, 2009  
Received: April 27, 2009

Dear Ms. White:

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); 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).

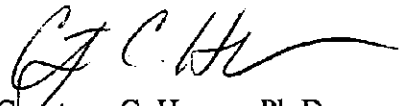
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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your 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" (21 CFR 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. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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,



Courtney C. Harper, Ph.D.  
Acting Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): k081938

Device Name: Acetaminophen L3K Assay

Indication For Use:

For the quantitative measurement of acetaminophen in serum and plasma. Measurement of acetaminophen is used in the diagnosis and treatment of acetaminophen overdose toxicity.

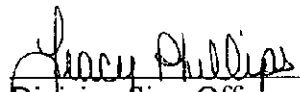
Prescription Use  X   
(21 CFR Part 801 Subpart D)

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)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)  k081938