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### 510(k) SUMMARY

#### Submitter's Name

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#### Product Name

Trade name-Urea Nitrogen (BUN) Liqui-UV®  
Common name-Urea Nitrogen (BUN)  
Classification name-Urease and Glutamic Dehydrogenase, Urea Nitrogen  
*Jim* **Class II, 75CDQ**

#### Substantial Equivalence of Device

This test is substantially equivalent to :  
Product Name: BUN, UV Urease/GLDH (Kinetic)  
Manufacturer: Boehringer Mannheim

#### Description of Device

The device test kit is comprised of two reagents, BUN Buffer (R1) and BUN Enzyme (R2), and a standard, 30mg/dL. A working reagent is prepared by combining five parts BUN Buffer (R1) to one part BUN Enzyme (R2).

#### Intended Use of Device

The device is used for the kinetic quantitative determination of Urea Nitrogen (BUN) in serum.

#### Comparison of Devices

Both Urea Nitrogen (BUN) methods measure kinetically the decrease in absorbance due to consumption and conversion of NADH to NAD.

#### Performance Data

Substantial equivalency was demonstrated by method comparison. Correlation was performed between the two test kits with a correlation coefficient of 0.999 and a regression equation of  $y = 1.012x - 0.47$ .

In addition, precision, linearity, sensitivity, stability and interference studies were performed on Stanbio Laboratory, Inc., version of Urea Nitrogen (BUN) Liqui-UV®, Catalog # 2020. Results of these tests were found to be acceptable.