

# BIOMERICA

510-K

## Summary Statement

Biomerica Inc., *EZ-HCG*<sup>™</sup> urine test device is a one step immuno-assay for a rapid, qualitative determination of human Chorionic Gonadotropin (hCG) in urine for early detection of pregnancy.

The device is an *in vitro diagnostic* test kit.

The *EZ-HCG*<sup>™</sup> test device consists of a chromatographic absorbent membrane strip and a combination of monoclonal and polyclonal antibodies that selectively identify hCG in test samples with a high degree of sensitivity. Within three minutes, levels of hCG as low as 25 mIU/ml can be detected.

Biomerica's *EZ-HCG*<sup>™</sup> is a generic type device using a plastic strip affixed with a porous membrane with two antibodies immobilized on it; a fiber glass pad soaked and dried with an antibody coupled with gold particles and a filter strip. The plastic strip is encased inside a plastic cassette with two windows – one for sample addition and the other for viewing the results.

Data submitted in this 510-K Premarket notification is correct and has been compared to be substantially equivalent to a 510(k) cleared commercially available predicate devices in the market, manufactured by Biomerica Inc., and Quidel Corporation, San Diego, California.

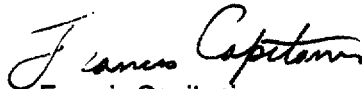
This device has no environmental impact.

The performance data and clinical data is on file and is available to any qualified individual upon request. Biomerica is responsible and attests that all information submitted is true and authentic to the best of our knowledge.

Sincerely,



Jay Singh  
Chief Operating Officer.



Francis Capitanio  
President.