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SUMMARY OF SAFETY AND EFFECTIVENESS

The sponsor Syntron Bioresearch Inc. (277 Loker Ave. West, Carlsbad, Ca., 92008) has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Cannabinoids and their metabolites in a screening format.

The Trade name of the device is QuikPac II™ One Step Marijuana (THC) Test having a designated common name of Cannabinoid Test System and a classification as a class II device per 21 CFR 862.3870. This device is intended for medical/forensic screening of urine.

Syntron's QuikPac II™ One Step Marijuana (THC) test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 50 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

The sponsor subjected the final product to both in house testing of 261 individual urine samples using both the Syva Emit and GC/MS against the new product and an independent Clinical Trial. The calculated relative sensitivity compared to Emit was 99.3% and the calculated relative specificity against Emit was found to be 1.00 with concordance of 99.67%. Statistical comparisons of all possible combinations of reference methods to the experimental new device failed to identify any significant difference Between the reference method and the new Syntron method.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, President of Drial Consultants Inc. at 415-688-0100 or by fax at 415-688-0104 who is Syntron's designated regulatory consultant. Specific Corporate information may be obtained from Dr. James Lee. President of Syntron Bioresearch at the address given in the first paragraph